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VIA ELECTRONIC FILING
Division of Dockets Management
Department of Health and Human Services
Food and Drug Administration
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UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES AND THE FOOD AND DRUG ADMINISTRATION

CITIZEN PETITION

Request that the Commissioner of Food and Drugs Immediately Request Intuitive Issue a Class I Recall of All Model 5 da Vinci Surgical Systems Due to a Serious Intraoperative Power Failure Defect Causing Prolonged Reboot Delay, Loss of Visualization and Control, and Potential Insufflation Loss in da Vinci 5 Models, Publish an Urgent Medical Device Safety Communication, and send a Warning Letter to Intuitive

The undersigned submit this petition under 21 C.F.R. §§ 10.20, 10.25, 10.30, 800-898; 21 U.S.C. § 301 et seq.; and the Administrative Procedure Act.

A. Action Requested

The undersigned request that the Commissioner of Food and Drugs and the Secretary of Health and Human Services (collectively "the FDA") take the following actions regarding the da Vinci Surgical Systems IS5000 and all iterations, manufactured by Intuitive Surgical, Inc. ("Intuitive"), with the problems identified in this petition:

1. immediately request Intuitive issue a Class I recall, with the context described below, da Vinci Surgical Systems model number IS5000[1] or any subsequent or associated 510(k) clearance (hereinafter "da Vinci 5") because of intermittent intraoperative power loss defect that poses a serious and persistent public health risk, and because there is a reasonable probability that the use of, or exposure to, a da Vinci 5 will cause serious adverse health consequences or death;

[1] U.S. Food & Drug Admin., 510(k) Premarket Notification (K232610), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K232610

2. immediately issue an urgent Medical Device Safety Communication, as described below, notifying the public, practitioners, hospitals, and surgical teams of the serious risk of power failure; and

3. investigate the identified issue and issue a warning letter to Intuitive Surgical, Inc. stating that Intuitive's da Vinci 5 violate federal regulations and that Intuitive must expeditiously develop, validate, and implement a definitive intrinsic engineering correction to the power vulnerability, as described below.

B. FDA Legal Authority to Act

The FDA possesses clear statutory and regulatory authority under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et seq.) to take each of the requested actions.

1. Recalls

The FDA has authority to request a recall.[2] Generally, when the FDA requests a recall from the manufacturer, the manufacturer's compliance is voluntary.[3] Before initiating a voluntary recall request, the FDA must make the following determinations:

> (1) That a product that has been distributed presents a risk of illness or injury or gross consumer deception.
>
> (2) That the firm has not initiated a recall of the product.
>
> (3) That an agency action is necessary to protect the public health and welfare.[4]

In determining whether to request a recall, the FDA must classify "relative degree of health hazard presented by" the device, which falls into three classes. A Class I recall "is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death."[5] Class II recall "is a situation in which use of, or exposure to, a violative [device] may cause temporary or medically reversible adverse

[2] 21 U.S.C. § 350l(a); 21 C.F.R. §§ 7.3.(g); 7.4
[3] 21 C.F.R. § 7.40.
[4] 21 C.F.R. § 7.45(a).
[5] 21 C.F.R. §§ 7.3.(m)(1).

health consequences or where the probability of adverse health consequences is remote."[6] A Class III recall "is a situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences."[7] The FDA considers the following list of non-exclusive factors when determining whether to request a recall and how to classify it:

> (1) Whether any disease or injuries have already occurred from the use of the product.
>
> (2) Whether any existing conditions could contribute to a clinical situation that could expose humans or animals to a health hazard. Any conclusion shall be supported as completely as possible by scientific documentation and/or statements that the conclusion is the opinion of the individual(s) making the health hazard determination.
>
> (3) Assessment of hazard to various segments of the population, e.g., children, surgical patients, pets, livestock, etc., who are expected to be exposed to the product being considered, with particular attention paid to the hazard to those individuals who may be at greatest risk.
>
> (4) Assessment of the degree of seriousness of the health hazard to which the populations at risk would be exposed.
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> (5) Assessment of the likelihood of occurrence of the hazard.
>
> (6) Assessment of the consequences (immediate or long-range) of occurrence of the hazard.[8]

2. Warning Letters, Adulteration, and Current Good Manufacturing Practices

The FDA also regulates manufacturing of medical devices, and can take regulatory action based on nonconformance to manufacturing regulation. Devices that do not conform to performance standards are adulterated.[9] The FDA sets performance standards for Class II and III devices using regulation.[10] Existing regulations require manufacturers of all devices comply

[6] 21 C.F.R. §§ 7.3(m)(2).
[7] 21 C.F.R. §§ 7.3(m)(3).
[8] 21 C.F.R. § 7.41(a).
[9] 21 U.S.C. 351(e).
[10] 21 U.S.C. § 360d (performance standards requirements for Class II devices).

with the Quality Management System Regulation ("QSMR")/current good manufacturing practices ("CGMP").[11] This includes a requirement to establish design controls for all Class II and III devices.[12] Design requirements include establishing and maintaining, among other things, procedures

- "to ensure that the design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the user and patient" (design input);[13]

- "for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements" (design output);[14]

- "to ensure that formal documented reviews of the design results are planned and conducted at appropriate stages of the device's design development" (design review);[15]

- "for verifying the device design" (design verification);[16] and

- "for validating the device design" (design validation).[17]

Moreover, the FDA has recognized ISO 14971:2019 as a consensus standard it follows in applying its regulations.[18] And it has endorsed this ISO in guidance documents[19] and stated that robotic surgery is "highest priority" device for human factors review.[20] This standard requires manufacturers to "establish, implement, document and maintain an ongoing process" for identifying "hazards and hazardous situations associated with a medical device,"[21] and

[11] 21 C.F.R. § 820.1. The QSMR became effective Feb. 2, 2026, expressly incorporating by reference ISO 13485:2016. For convenience, we refer to relevant regulations as the CGMP for the remainder of the petition.

[12] 21 C.F.R. § 820.30.

[13] 21 C.F.R. § 820.30(c).

[14] 21 C.F.R. § 820.30(d).

[15] 21 C.F.R. § 820.30(e).

[16] 21 C.F.R. § 820.30(f)

[17] 21 C.F.R. § 820.30(g)

[18] Recognized Consensus Standards: Medical Devices, FR Recognition Number, 5-125, ISO 14971: 2019, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/detail.cfm?standard__identification_no=41349&utm.

[19] FDA, Applying Human Factors and Usability Engineering to Medical Devices: Draft Guidance for Industry and Food and Drug Administration Staff 1–2 (Feb. 3, 2016) https://www.fda.gov/media/80481/download.

[20] Draft Guidance for Industry and Food and Drug Administration Staff, issued Feb 3, 2016; non-binding, not for implementation)

[21] ISO 14971 § 4.1.

estimating, controlling, and monitoring them.[22] "Hazards" include potential sources of harm, defined as injury or damage to health of people, or damage to property or the environment.[23]

Examples of hazards included are "energy hazards," which include power failures.[24] Just like under FDA regulations, under ISO 14971, manufacturers are responsible for risk (and residual risk) analysis,[25] evaluation,[26] control,[27] and implementation.[28] When residual risk after implementation is unacceptable, the manufacturer must begin the process again. Finally, the ISO notes that other standards may be applied for specific types of risks, such as IEC 60601-1 (basic safety and essential performance), 60601-1-2 (electromagnetic disturbances), 60601-1-2-18 (endoscopic equipment interactions), 60601-2-2 (high frequency surgical equipment), and 60825-1 (laser safety). And specific risks include risks associated with intended uses, such as power failures, and reasonably foreseeable misuses.[29]

3. Communication

The FDA has authority to issue letters to healthcare providers and warnings under Food, Drug, & Cosmetic Act. The FDA regularly issues Medical Device Safety Communications, Public Health Notifications, and Dear Health Care Provider letters to warn of known hazards and inadequate mitigations without requiring a formal recall under its inherent authority as regulator of medical devices. 21 U.S.C. § 301 et seq.

C. Statement of Grounds

This section explains why the FDA should grant the requests in this petition. In particular, it explains (1) background on the da Vinci and its defect, (2) preliminary data showing the defect is widespread, and (3) argument for why this defect requires the requested action.

1. Background

da Vinci Surgical Systems and the Acknowledged Defect

[22] ISO 14971 § 4.1.
[23] ISO 14971 §§ 3.3, 3.4.
[24] ISO 14971 Table C.1.
[25] ISO 14971 § 5.
[26] ISO 14971 § 6.
[27] ISO 14971 § 7.
[28] ISO 14971 § 7.2.
[29] ISO 14971 § A.2.5. *See also* Guidance in ISO/TR 24971:2020 (interpreting ISO 14971).

The da Vinci Surgical Systems are computer-assisted, electromechanical robotic platforms intended for use in minimally invasive surgical procedures across multiple specialties (urologic, gynecologic, thoracic, general, and increasingly cardiac). Intuitive manufactures several models of its da Vinci System, including the da Vinci 5. In 2025, Intuitive reported it placed in health care facilities 870 da Vinci 5 models, more than doubling the 362 placed in 2024.[30] Since its inception, Intuitive reports that "[m]ore than 12 million procedures have so far been performed using Intuitive robotic systems."[31]

Because the da Vinci 5 is a complicated device, it has a number of components that can malfunction or not perform as expected. One predictable issue for complex surgical robots like the da Vinci 5 is that they require a constant supply of electricity. Without power, the device cannot operate. If the device loses power during a procedure, the patient and hospital staff can be put at serious risk of injury or death. The system requires 4 (or 5 if an optional second console is used) external power outlets.

To satisfy the FDA requirements of premarket notification and obtain market access, Intuitive represented to the FDA that it had complied with all relevant regulations and conducted the following electrical safety and electromagnetic compatibility testing:

> Electrical Safety and Electromagnetic Compatibility testing was conducted using a third-party lab in accordance with the current versions of
>
> IEC 60601-1 (basic safety and essential performance),
> IEC 60601-1-2 (Electromagnetic disturbances),
> IEC 60601-2-18 (Endoscopic equipment interactions),
> IEC 60601-2-2 (high frequency surgical equipment), and
> IEC 60825-1 (laser safety).[32]

Despite this representation, the da Vinci 5 has experienced power-related problems. On, December 12, 2024, Intuitive Surgical, Inc. issued a formal customer notification letter that explicitly acknowledged a systemic vulnerability.[33] It explained that power fluctuations—common in hospital environments due to severe weather, excessive power demand, backup generator testing/transfer, or wall outlet malfunctions—can trigger repeated interruptions,

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[30] Fintool Agent, *Intuitive Surgical Crosses $10 Billion in Revenue, Stock Falls on Slowing Growth Outlook*, (Jan. 15, 2026), https://fintool.com/news/intuitive-surgical-10b-revenue-stock-falls.

[31] *The Rapid Growth of the da Vinci Surgeon Community | Intuitive*, https://www.intuitive.com/en-us/about-us/newsroom/growth-of-da-vinci-surgeons (last visited Feb. 4, 2026).

[32] U.S. Food & Drug Admin., 510(k) Premarket Notification (K232610), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K232610

[33] Intuitive Surgical Customer Letter, MAT06450 v1 US 12/2024, attached as Exhibit A.

cause damage to critical circuit boards (preventing booting and requiring field engineer replacement), and necessitate complete system rebooting or downtime. Despite these significant risks and their intrinsic nature, the letter recommends only extrinsic mitigations: daily power-down/unplugging of Tower/Console cables, circuit breaker flipping routines, or external uninterruptible power supply (UPS) units matched to exact specifications per the user manual.

Integration of Insufflator in da Vinci 5 Tower Architecture

In the da Vinci 5, the carbon dioxide insufflator (with smoke evacuation capabilities) is integrated into the system's unified tower architecture, which houses key components including the vision system, E-200 electrosurgical generator, processors, and electronics.[34] This consolidation shares the overall power infrastructure of the platform, with the tower requiring dedicated electrical circuits (115 VAC or 230 VAC) and warnings against sharing with high-power devices due to its large power draw. There is no separate, independent power circuit for the insufflator. Consequently, a total loss of power to the system (facility blackout or main circuit failure) affects the entire tower, including the insufflator, potentially compromising active insufflation and pneumoperitoneum maintenance during procedures.

Detailed Analysis of the Defect's Intraoperative Risks and Mechanisms

When power loss occurs during an active procedure, the system undergoes a forced reboot that results in a prolonged delay, during which the surgeon experiences total loss of endoscopic visualization and remote control over all intracorporeal instruments. During this "blackout," all instruments remain inside the patient in close proximity to vital structures (major blood vessels, bowel, ureters, nerves). In the newer da Vinci 5 models, adverse event data and user reports indicate associated disruption of insufflation (pneumoperitoneum maintenance), leading to rapid deflation of the abdominal cavity. This combination creates an acute "blind" and potentially collapsed operative field, dramatically elevating the risk of catastrophic complications such as uncontrolled hemorrhage, inadvertent organ/vessel laceration, unintended instrument activation or movement, prolonged anesthesia exposure, conversion to open surgery under duress, or death—particularly in high-risk procedures like cardiac surgery where the da Vinci 5 is used.

2. <u>Evidence from FDA's MAUDE Database and Persistent Adverse Event Reports</u>

[34] U.S. Food & Drug Administration, 510(k) Premarket Notification (K232610), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K232610.

FDA's Manufacturer and User Facility Device Experience ("MAUDE") database contains numerous reports documenting power-related malfunctions in da Vinci systems (including da Vinci 5 variants) from 2024 through late 2025.[35] These include descriptions of intraoperative power outages requiring hard reboots, loss of vision/control, faulty power converters or redundant power trays, battery/run-on-battery error messages mid-procedure, communication faults, and associated delays or complications. These reports are not isolated but reflect an ongoing pattern that the manufacturer's extrinsic recommendations have failed to fully resolve.

To better understand the scope of the risks, we ran searches of the MAUDE database on a proprietary platform. We searched devices by "davinci", "da vinci", or "robotic-assisted" product to filter for da Vinci products. The additional search terms "powered off", "energy output problem", "shutdown", "unexpected shutdown", or "power problem" were added to filter for instances when the device had an unexpected power issue. 16 keywords were added, such as "shutdown during", "aborted", and "hospitalization", to further refine the search and provide the final 2,435 results.[36] After sorting for reports by "FDA received date" to those received after January 1, 2025, 928 remained. After filtering reports by K232610, 50 remained. Manual review of these results showed that at least 17, but possibly up to 35, of these events related to the problem identified in this petition.[37]

Given the seriousness of the problem and the potential risk to patients and surgeons, we have chosen to include 15 examples as a preliminary representation of our examination of reports related to incidents with da Vinci 5. It is important to note, however, that not all reports are linked to a 510(k) number or the correct 510(k) number.[38] The excerpts of MAUDE reports below, therefore, represent an incomplete picture of the power failure issue and its potential risk:

- During "a da vinci-assisted surgical procedure, the system shut down during the case . . . ."[39]

[35] *See* Exhibit B.

[36] Relevant MDR numbers and manufacturer summaries are listed in Exhibit B.

[37] See attached Exhibit B.

[38] One example is U.S. Food & Drug Admin., MAUDE Adverse Event Report: INTUITIVE SURGICAL, INC, DAVINCI XI; PATIENT SIDE CART, 4-ARM (MDR Report Key 19069043, Report No. 2955842-2024-13121, event Mar. 13, 2024; FDA received Apr. 9, 2024, supplement received May 6, 2024), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/Detail.cfm?MDRFOI__ID=19069043 (power failure but no associated 510(k) number listed).

[39] Report Number: 2955842-2025-16718.

- "prior to the start (post ports placement) of a da vinci-assisted unilateral inguinal hernia surgical procedure, the customer experienced a loss of vision, and the consoles indicated a need to restart. The customer attempted to restart the primary console, which successfully rebooted, but the other console, tower, and robot did not respond. The customer stated that there were no errors or messages prior to the vision loss."[40]

- "during a da vinci-assisted sleeve gastrectomy surgical procedure, the customer encountered errors after a power outage. The site did a few power cycles, breaker resets, and emergency power offs (epo) with no resolve. The site informed they were going to proceed laparoscopically."[41]

- "after a loss of power in the operating room, the system experienced non-recoverable errors. The technical support engineer was contacted to troubleshoot the issue. Upon attempting to power up the system after the loss of ac power, the system faulted, and the tower display remained blank . . . the customer converted the procedure to continue non-robotically…"[42]

- "during a da vinci-assisted surgical procedure, the vision tower lost power during a procedure. . . . Later, it was reported that the system would not power on together after power was restored to the room, with the robot not connecting to the system. Despite attempting three separate hard power cycles, the system failed to power up together. The staff chose to complete the procedure using an alternative system…"[43]

- "during a da vinci-assisted surgical procedure, . . . the customer can??t get the system to power up normal. The csr later contacted the tse and reported the staff had tried to power each component up in stand-alone mode and the vision side cart (vsc) and the surgeon side console (ssc) would only show a flashing blue power button. The procedure was converted to laparoscopic surgery… \nIt was reported that during a da vinci-assisted surgical procedure, the clinical sales representative (csr) contacted the technical support engineer (tse) from offsite to report that the system had power issue due to room power. . . . . The csr stated the customer can?t get the system to power up normal. The csr later contacted the tse and reported the staff had tried to power each component up

[40] Report Number: 2955842-2025-49647.
[41] Report Number: 2955842-2025-49016.
[42] Report Number: 2955842-2025-43726.
[43] Report Number: 2955842-2025-34901.

in stand-alone mode and the vision side cart (vsc) and the surgeon side console (ssc) would only show a flashing blue power button. The procedure was converted to laparoscopic surgery. . . . [After Intuitive inspection,] [s]ystem could not fully power on and had "insufflator disabled" message on the vsc touch screen. The ccc was taken to a programming station where it was confirmed to be bricked. The root cause was attributed to a bricked ccc."[44]

- "there was a power outage in the hospital, and the system would not complete the power-on self-test. The customer attempted a power cycle before calling but was unsuccessful. The customer then performed a hard power cycle on the system, which resulted in the system coming back up with a 40096 error. The customer was unable to access the pop-up logs, and the system logs were not available. Consequently, the customer put the patient side cart (psc) into manual mode to undock and complete the case laparoscopically.\nAn investigation was completed to determine the cause of this reported event."[45]

- "during a da vinci-assisted surgical procedure, the customer contacted the technical support engineer (tse) to report that they have a robot not connected or powered message. Prior to calling in, customer had power cycled system, but message continued. Tse walked caller through an additional hard power cycle, emergency power off (epo) the system and had caller verify connection of blue fiber cable between tower and robot. System powered back on without error message but errored again 15 seconds later with a 170 error. Tse then had customer take blue fiber cable from another system and install new cable at the open tower fiber port and route to the robot. Once again, the system powered back on without error, but error returned 15 seconds later. The procedure was converted to another dv system. Intuitive surgical, inc. (isi) followed up with the initial reporter and obtained the following additional information: the initial reporter confirmed that the issue happened during procedure, and the procedure was completed robotically using another system…"[46]

- "during a da vinci-assisted surgical procedure, the system experienced a fault and shut down. The site was initially able to power the system back on and proceed. The customer then informed that the patient was then transported from one operating room (or) to a different or to attempt to complete the

[44] Report Number: 2955842-2025-00039.
[45] Report Number: 2955842-2025-46564.
[46] Report Number: 2955842-2025-44038.

procedure with a different da vinci; however, that was unsuccessful, and the patient was transferred to a different facility."[47]

- "It was reported that during a da vinci-assisted surgical procedure, the customer contacted the technical support engineer (tse) and reported that the vision tower was not powering back completely following a power outage. After multiple power cycles and breaker resets, the vison tower did not power up and displayed indicating 'insufflator disabled'. When powering off the system, the vision side cart (vsc) did not respond correctly. The power button was activated, but the system did not countdown. Both observations are indicative of a faulty common computer controller (ccc) board within the vsc. The customer replaced the vsc and connected with another system sq0616 to finish this case. This was classified as down vsc event. The procedure was converted to another dv system with no reported injury.\nAn intuitive surgical, inc. (isi) field service engineer (fse) was dispatched to the customer site to further investigate the reported event. The fse was able to reproduce the error. The fse replaced the vision side cart (vsc)common computer controller (ccc) to resolve the issue. The system was tested and verified as ready for use. Isi did not receive the da vinci product involved with this complaint to perform failure analysis."[48]

- "the customer received an error that caused the system to reboot in the middle of a case. The surgeon had lost all vision and controls. After rebooting the system, the customer was able to complete the case. . . . the machine learning xavier (mlx) was received and failure analysis confirmed but could not replicate the reported event. The mlx was visually inspected with no issues relating to the complaint being found. Upon review of the error logs, several errors were found. . . . "while performing a robotic lymph node dissection around some very large pulsating vessels in the chest cavity, the robot announced out loud 'prepare for the davinci to shutdown/reboot' soon after the robot beeped as if it would during shut down. This happened pretty quick without warning. The robot then rebooted a few moments later. During this time the robot screens went black, and the robotic arms were frozen in place and could not be removed . . . ."[49]

- "during a da vinci-assisted surgical procedure, the power went out. There was a needle driver in the abdominal wall. They powered the system back on and an error message says the console is not connected to the tower and they have no

[47] Report Number: 2955842-2025-43313.
[48] Report Number: 2955842-2025-41863.
[49] Report Number: 2955842-2025-22274.

visual. Technical support engineer (tse) walked caller through hard power cycle on console and system came back up normally. The caller said the camera was flipped upside down and backwards and surgeon said he could not control any of the arms, message says to undock arms and redock when ready. Tse had caller reseat the camera. The procedure was completed with no reported injury."[50]

- "during a da vinci-assisted benign hysterectomy surgical procedure, the clinical sales representative (csr) contacted the technical support engineer (tse) to report that they were having lots of issues with the insufflator. The insufflator turned off on its own. Then after that they tried five different lots of tube sets and could not get one of them to be valid with the insufflator. She stated that this had been an ongoing issue with the system. The customer quit trying to get it to work and started using the airseal for the case. The procedure was completing as planned with no reported injury…"[51]

- "during a da vinci-assisted surgical procedure, the customer contacted the technical support engineer (tse) to report that the system faulted and shut down. Customer stated that prior to the system fault, the surgeon was activating energy. When the system powered off, the surgeon removed their foot from the pedal but energy was still being delivered. Customer stated that after a couple of attempts, they were able to finally power the system back on. The procedure was completed with no reported injury. Intuitive surgical, inc. (isi) followed up with the initial reporter and obtained the following additional information: the surgeon said the system shut down and the surgeon removed their foot from the pedal, but energy was still being delivered. The energy was delivered for 2-3 seconds. The issue did not cause any injury/harm to the patient. The instrument the energy was being delivered was a bipolar instrument. The system was powered back on and the procedure was completed robotically.\nThe video interface patch panel (vip) at the vision side cart was returned and evaluated by the failure analysis (fa) team who performed a visual inspection and found no problem related reported issue. Fa checked and confirmed error codes 307 and 48305 in lighthouse, then installed in an internal fixture, or tool (eft) system. During system testing was unable to replicate reported issue (could not replicate). No root cause is determined at this time. Intuitive surgical, inc. (isi) received medwatch# 5174644 and obtained the following additional information: while the surgeon was operating robot from the console, he was unable to control the robot. The robot has the restart option. Upon first restart,

[50] Report Number: 2955842-2025-16476.

[51] Report Number: 2955842-2025-01622.

the sound of cautery stopped. The robot required two separate restarts before correcting the issue. Da vinci representative was notified of the issue. Intuitive surgical, inc. (isi) followed up with the customer and obtained the following additional information: the medwatch#5174644 report was referring to the same issue. There was no non-intuitive motion experienced. Field h8 corrected to initial use. Field a3 gender corrected to male.\nAn intuitive surgical, inc. (isi) field service engineer (fse) was dispatched to the customer site to further investigate the reported event. The fse was able to reproduce the issue. The field service engineer (fse) replaced the vip, vision side cart (vsc) to resolve the 307 error. The system was tested and verified as ready for use. Isi did receive the unit involved with this complaint to perform failure analysis; however, failure analysis has not completed their investigation.\nRefer to h11 for follow-up information."[52]

- "It was reported that the or staff experienced a system shutdown mid-case due to a power loss. Upon restarting, the 30-degree endoscope was upside down and could not be corrected. The staff used another 30-degree scope to continue the procedure."[53]

3. Why FDA Action is Required

This section first explains why a recall is necessary and appropriate. It then argues that a Class I recall is the most appropriate level recall. The section concludes with a discussion of why the device is adulterated and requires additional warnings to Intuitive, healthcare providers, and the public.

Recall is Necessary

The FDA should request that Intuitive issue a voluntary recall because the da Vinci 5 "presents a risk of illness or injury or gross consumer deception."[54] When a power failure occurs during a surgery, any of the following are possible:

[52] Report Number: 2955842-2025-36597.
[53] Report Number: 2955842-2025-48607.
[54] 21 C.F.R. § 7.45(a)(1).

- a robot arm may reset and automatically reposition inside the patient,[55]
- the insufflator fails, deflating the patient tissue and collapsing the visual and surgical fields;[56]
- the physician loses their entire electronic visual and surgical field,[57]
- devices used interoperatively may become stuck in the patient or in positions that are dangerous to the patient;[58]
- significant operative delays;[59]
- the surgery may need to be converted to an "open" or alternative procedure;[60] and/or
- the surgery may need to be aborted.[61]

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[55] U.S. Food & Drug Admin., MAUDE Adverse Event Report: INTUITIVE SURGICAL, INC, NONE; ENDOSCOPE (MDR Report Key 23809679, Report No. 2955842-2025-48607, event Nov. 24, 2025; FDA received Dec. 15, 2025), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/Detail.cfm?MDRFOI__ID=23809679&pc=NAY.

[56] U.S. Food & Drug Admin., MAUDE Adverse Event Report: INTUITIVE SURGICAL, INC, DA VINCI 5; VISION SIDE CART (MDR Report Key 23317855, Report No. 2955842-2025-41863, event Sept. 24, 2025; FDA received Oct. 16, 2025; supplement received Nov. 12, 2025), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/Detail.cfm?MDRFOI__ID=23317855&pc=NAY ("After multiple power cycles and breaker resets, the vison tower did not power up and displayed indicating 'insufflator disabled'.") U.S. Food & Drug Admin., MAUDE Adverse Event Report: INTUITIVE SURGICAL, INC, DA VINCI 5; ENDOWRIST MONOPOLAR CURVE TIP SCISSOR (MDR Report Key 21071654, Report No. 2955842-2025-00102, event Nov. 18, 2024; FDA received Jan. 2, 2025 & supplement received Feb. 7, 2025), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/Detail.cfm?MDRFOI__ID=21071654&pc=NAY ("The ccc was installed on the known good in-house system and the vision side cart (vsc) monitor could not show full display on the screen. System could not fully power on and had "insufflator disabled" message on the vsc touch screen.")

[57] U.S. Food & Drug Admin., MAUDE Adverse Event Report: INTUITIVE SURGICAL, INC, DA VINCI 5; VISION SIDE CART, MDR Report Key 23890022 (Dec. 24, 2025), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/Detail.cfm?MDRFOI__ID=23890022&pc=NAY.

[58] U.S. Food & Drug Admin., MAUDE Adverse Event Report (MDR Report Key 21095773), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/Detail.cfm?MDRFOI__ID=21095773&pc=NAY; U.S. Food & Drug Admin., MAUDE Adverse Event Report (MDR Report Key 21572714), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/Detail.cfm?MDRFOI__ID=21572714&pc=NAY.

[59] U.S. Food & Drug Admin., MAUDE Adverse Event Report: INTUITIVE SURGICAL, INC, DAVINCI 5; PATIENT SIDE CART (MDR Report Key 21095773, Report No. 2955842-2025-00162, received by FDA Feb. 12, 2025), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/Detail.cfm?MDRFOI__ID=21095773&pc=NAY (25-30 minute delay)

[60] U.S. Food & Drug Admin., MAUDE Adverse Event Report: INTUITIVE SURGICAL, INC, DAVINCI 5; VISION SIDE CART (MDR Report Key 23845164, Report No. 2955842-2025-49016, reported event Dec. 8, 2025; FDA received Dec. 18, 2025), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/Detail.cfm?MDRFOI__ID=23845164&pc=NAY (converted to laparoscopy); U.S. Food & Drug Admin., MAUDE Adverse Event Report: INTUITIVE SURGICAL, INC, DA VINCI 5; VISION SIDE CART (MDR Report Key 23500380, Report No. 2955842-2025-44563, report received by FDA Dec. 8, 2025), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/Detail.cfm?MDRFOI__ID=23500380&pc=NAY (converted to open)

[61] U.S. Food & Drug Administration, MAUDE Adverse Event Report: INTUITIVE SURGICAL, INC, DAVINCI 5; PATIENT SIDE CART (MDR Report Key 23434949, Report No. 2955842-2025-43313, event Oct. 5, 2025; FDA received Oct. 31, 2025; supplement received Dec. 4, 2025), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/Detail.cfm?MDRFOI__ID=23434949&pc=NAY (patient transferred to another facility after device power problem); *see* U.S. Food & Drug Admin., MAUDE Adverse Event Report: INTUITIVE SURGICAL, INC, DA VINCI 5; PATIENT SIDE CART (MDR Report Key 21095773, Report No. 2955842-2025-00162, event Dec. 12, 2024, FDA received Jan. 7, 2025 & supplement received Feb. 12, 2025),

If any of these occurs, the patient could be seriously injured or killed.

Second, the "firm has not initiated a recall of the product."[62] Intuitive has so far issued only the letter to health care providers but has not issued a recall.

Third, a recall is "necessary to protect the public health and welfare."[63] Without a recall, the da Vinci 5 will remain on the market. Additionally, Intuitive has effectively disclaimed responsibility by placing the corrective action on health care facilities, many of which may not be aware of the power supply problem.

Class I Recall Is Required

The FDA should request Intuitive issue a Class I recall because sudden loss of power "is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death."[64]

Each of the factors the FDA evaluates to classify a recall point toward a Class I recall. First, the product has already caused injuries.[65] For example, in one procedure the gallbladder was injured.[66] In another, the patient's operation had to be aborted and the patient had to be transferred to another facility.[67] In many others, procedures have been converted to open or laparoscopic.

Second, "existing conditions could contribute to a clinical situation that could expose humans . . . to a health hazard."[68] When surgeons lose the ability to operate suddenly, the patient being operated on is placed at immediate risk.

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https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/Detail.cfm?MDRFOI__ID=21095773&pc=NAY (aborted to laparoscopic)

[62] 21 C.F.R. § 7.45(a)(2).

[63] 21 C.F.R. § 7.45(a)(3).

[64] 21 C.F.R. §§ 7.3.(m)(1).

[65] 21 C.F.R. § 7.41(a)(1).

[66] U.S. Food & Drug Admin., MAUDE Adverse Event Report (MDR Report Key 21095773), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/Detail.cfm?MDRFOI__ID=21095773&pc=NAY; U.S. Food & Drug Admin., MAUDE Adverse Event Report (MDR Report Key 21572714), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/Detail.cfm?MDRFOI__ID=21572714&pc=NAY.

[67] U.S. Food & Drug Administration, MAUDE Adverse Event Report: INTUITIVE SURGICAL, INC, DAVINCI 5; PATIENT SIDE CART (MDR Report Key 23434949, Report No. 2955842-2025-43313, event Oct. 5, 2025; FDA received Oct. 31, 2025; supplement received Dec. 4, 2025), (patient transferred to another facility after device power problem);

[68] 21 C.F.R. § 7.41(a)(2).

Third, an assessment of the "hazard to various segments of the population" shows that the da Vinci robot is in widespread use.[69] According to Intuitive, "approximately 2,683,000 surgical procedures were performed with da Vinci surgical systems" in 2024.[70]

Fourth the "degree of seriousness of the health hazard to which the populations at risk would be exposed" is extremely high.[71] Even a brief power outage places the patient's life at risk. The da Vinci 5 creates the operative field for robot-assisted operations. When the device loses power, the operative field is abolished, and both the surgeon and patient are left in a dangerous "blackout" with no control. For example, if the loss of surgical control occurs during a critical juncture—e.g., obtaining hemostasis, dividing or moving blood vessels, nerves, etc.—the patient could be seriously injured or die. Although there is limited data about the length of time required for a power reboot, the time could vary between 2 to 30 minutes, assuming no circuit board replacement is required. One reason time cannot be reliably estimated is because some surgeons must abandon the reboot and abort and/or convert the procedure emergently.

Fifth, the hazard is likely to recur.[72] Intuitive has already notified providers of the problem, suggesting the occurrence is likely to occur in all of its da Vinci 5 models deployed throughout the United States.

Sixth, the immediate consequences of this product problem are obvious, substantial, and foreseeable—patients could be injured, die, or suffer other adverse surgical outcomes.[73] Aborting one procedure for another introduces a greater risk of infection and increases the size of surgical area, potentially leading to more complications. Loss of power can also jeopardize key blood vessels and nerves that the surgeon is articulating, dividing, or manipulating—leaving the surgeon without control and potentially severing key structures. Concurrent loss of insufflation with da Vinci 5 adds an additional layer of risk.

FDA Warning Is Required for An Adulterated Device

The FDA should warn Intuitive, healthcare providers, and the public that the da Vinci 5 power failure vulnerability violates CGMP—including ISO 14971—which renders the device adulterated. The da Vinci 5 falls squarely within the risk contemplated by the CGMP. Specifically, Intuitive has not complied with design control requirements that require it to

[69] 21 C.F.R. § 7.41(a)(3).

[70] *Intuitive Announces Preliminary Fourth Quarter and Full Year 2024 Results | Intuitive Surgical*, https://isrg.intuitive.com/news-releases/news-release-details/intuitive-announces-preliminary-fourth-quarter-and-full-year-4/ (last visited Feb. 4, 2026).

[71] 21 C.F.R. § 7.41(a)(4).

[72] 21 C.F.R. § 7.41(a)(5).

[73] 21 C.F.R. § 7.41(a)(6).

establish and maintain procedures for design input, output, review, verification, and validation.

Consider first design inputs, which CGMP require procedures "appropriate . . . to address the intended use of the device, including the needs of the user and the patient."[74] So far, it appears Intuitive has not maintained an appropriate design controls to address the intended use of the device. The problem of inputs is known—power fluctuations could cause a malfunction, error, or other problem with the device, as described above.

Second, Intuitive does not appear to have complied with design output requirements under the CGMP, which require addressing foreseeable risks, such as power surges and fluctuations.[75] A proper design output that addresses risks posed by the device's intended use include features like backup power supply, redundant power supply, rapid recovery mechanisms, and fail-safe hardware to ensure equipment does not move after losing power.[76]

Finally, Intuitive seems to have not verified or validated device designs given the known power issues. Indeed, Intuitive's letter implies that it will not fix the known problem and will instead rely on others to avoid the risk. For example, the Letter recommends external UPS deployment, daily unplugging, or circuit breaker flipping. These are all extrinsic, user-dependent, and insufficient. Effective protection depends on consistent hospital electrical engineering support, correct UPS selection/sizing/maintenance, staff adherence to protocols, and uninterrupted availability—none of which are guaranteed. Many facilities may lack resources for fleet-wide compliant UPS installation, and even properly installed units can fail or be bypassed. Critically, no public evidence exists that Intuitive Surgical has incorporated intrinsic design-level corrections (redundant internal power supplies, automatic seamless failover, firmware enabling rapid recovery of visualization/insufflation, or extended onboard battery bridging sufficient for operative continuity during interruptions).

This reliance on extrinsic measures represents an unacceptable post-market workaround rather than a true corrective action. Recent U.S. power grid challenges (increasing surges/losses) further exacerbate risks, rendering extrinsic reliance unacceptable for critical operations. The absence of intrinsic safeguards—despite foreseeable power instability in real-world clinical settings—violates fundamental risk management principles that prioritize built-

[74] 21 C.F.R. § 820.30(c).

[75] 21 C.F.R. § 820.30(d).

[76] Indeed, Intuitive recognizes the need for reliable backup and redundant power supply: its current model has a battery. Unfortunately, the battery does not protect patients or remedy the current power supply problem. Intuitive Surigical da Vinci 5 System User Manual, at *488, at https://manuals.intuitivesurgical.com/c/document_library/get_file?uuid=8e613381-fb72-5092-f77e-ddaa74ac58fd&groupId=73750789.

in hazard elimination over reliance on external infrastructure or procedural compliance, which are inherently variable and prone to human or systemic error.

Given Intuitive's knowledge of the power supply problem, the adverse event reports in MAUDE, the high-stakes nature of robotic surgery (procedures often involving complex anatomy and critical structures), and the absence of any FDA recall, public communication, or warning letter concerning this specific hazard, urgent regulatory intervention is warranted. The FDA should send this alert to healthcare providers and should issue a public communication about the malfunction. Additionally, the FDA should issue a warning letter to Intuitive if it finds that the manufacturer is not in compliance with CGMP.

D. Summary of Actions Requested and Grounds

This petition requests that the FDA take the following actions regarding the da Vinci 5 and all iterations, manufactured Intuitive:

4. immediately request Intuitive issue a Class I recall, with the context described above, da Vinci Surgical Systems model number IS5000[77] or any subsequent or associated 510(k) clearance (hereinafter "da Vinci 5") because of intermittent intraoperative power loss defect that poses a serious and persistent public health risk, and there is a reasonable probability that the use of, or exposure to, a da Vinci 5 will cause serious adverse health consequences or death;

1. immediately issue an urgent Medical Device Safety Communication, as described below, notifying the public, practitioners, hospitals, and surgical teams of the serious risk of power failure; and

2. investigate the identified issue and issue a warning letter to Intuitive Surgical, Inc. stating that the company's device violates federal regulations to expeditiously develop, validate, and implement a definitive intrinsic engineering correction to the power vulnerability, as described above.

Each of these communications must clearly and explicitly describe

[77] U.S. Food & Drug Admin., 510(k) Premarket Notification (K232610), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K232610

- the nature of the power failure defect as acknowledged by the manufacturer, the intraoperative risks including prolonged periods of surgical "blindness" with powered instruments remaining inside the patient near critical vascular, organ, or neural structures;
- the potential for associated insufflation loss in newer models leading to rapid collapse of the operative field, the inadequacy and limitations of the manufacturer's recommended extrinsic mitigations (external uninterruptible power supplies or daily unplugging routines); and
- interim recommendations for heightened clinical vigilance, risk-benefit reassessment, or temporary suspension of non-emergent robotic procedures until intrinsic corrections are implemented and verified.

E. Environmental Impact

This petition is subject to the Statutory Exemption.

F. Economic Impact

This information can be furnished to the FDA commissioner upon request.

G. Certification

The undersigned certify that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

/s/ Hooman Noorchashm
Hooman Noorchashm MD, PhD, President, Harmed Americans for Reform in Medical-Device Safety Corp. (HARMS)

/s/ Michael K. Paasche-Orlow
Michael K. Paasche-Orlow MD, MA, MPH, Treasurer, Harmed Americans for Reform in Medical-Device Safety Corp. (HARMS)

/s/ David A. Simon

David A. Simon PhD, JD, LLM, Clerk, Harmed Americans for Reform in Medical-Device Safety Corp. (HARMS)

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143 Main St.
P.O. Box 7
Maynard, MA 01754

EXHIBIT A

INTUITIVE

Da Vinci 5 system announcement

Dear customer,

We're writing to let you know about a situation that can cause the da Vinci 5 surgical system to not turn on.

The issue occurs when there are repeated interruptions to the **wall outlet** power supply, which in turn could prevent a circuit board from booting the system. This circuit board needs to be replaced by an Intuitive field service engineer before you can turn the system on again.

A drop in voltage to the da Vinci 5 system can be caused by severe weather, excessive power demand, backup power generator testing, or a malfunction in the wall outlet power supply.

What can you do to stop this situation happening?

Power down the system and **unplug the power cable for the Tower and Console from the wall outlet at the end of the day**, particularly if a backup generator test is scheduled. In the morning, plug the system back in as part of your daily setup routine.

Alternatively, flip the circuit breaker on the Tower and Console to "off" at the end of the day. In the morning, flip the circuit breakers back "on" as part of your daily setup routine.

What else can you do?

Use an uninterruptible power supply (UPS) device for the da Vinci 5 Tower and Console to minimize incidences of unstable wall outlet power. The power and electric current outputs of the UPS should match the power requirements for the da Vinci 5 carts, as documented in the user manual (Table 4: System power cords and power requirements).

What are we doing to help solve the problem?

Our engineering team is investigating the issue and developing ways to make the system

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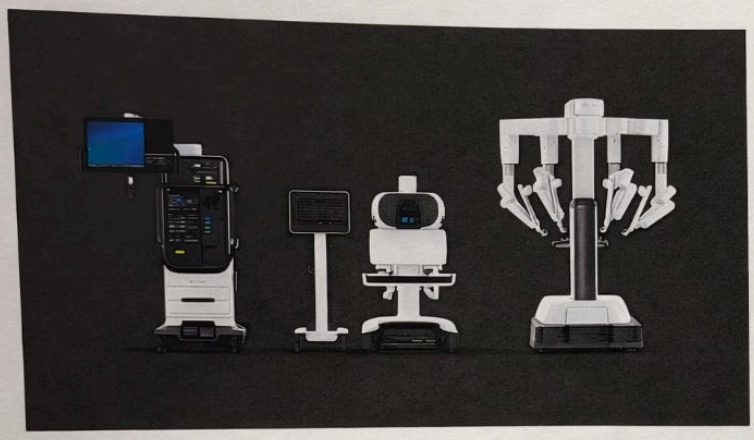
INTUITIVE

more robust in the event of unstable wall outlet power. We're looking to implement improvements as soon as possible.



Thank you for your attention to this matter. If you have any questions, please don't hesitate to contact our 24x7 support team at 1-800-876-1310.

Sincerely,

EXHIBIT B

Link to Dataset