VIA ELECTRONIC FILING

February 18, 2026

Division of Dockets Management
Department of Health and Human Services
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

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 Rescind or Amend 510(k) Clearance K252675 (December 15, 2025) for the da Vinci SP Surgical System by Removing "Nipple Sparing Mastectomy (NSM) Procedures" from Indications for Use Until Long-Term Oncologic Safety and Non-Inferiority Data Are Established, Restore the 2019 and 2021 Safety Communications, Issue Updated Guidance, and Conduct an Internal Review of Clearance K252675

The undersigned submit this petition under 21 C.F.R. §§ 10.20, 10.25, 10.30, and the Administrative Procedure Act (5 U.S.C. § 706), to request that the Commissioner of Food and Drugs and the Secretary of Health and Human Services immediately rescind or amend 510(k) clearance K252675, dated December 15, 2025, for the da Vinci SP Surgical System (Model SP1098) ("the Cleared Device" or "the K252675 clearance") by removing the addition of "nipple sparing mastectomy (NSM) procedures" from the indications for use. Additionally, the undersigned request that the FDA restore the agency's February 28, 2019, and August 20, 2021, Safety Communications (removed in 2024) cautioning against robotically-assisted surgical (RAS) devices in mastectomy for prevention or treatment of breast cancer. It should also issue Updated Guidance or a new safety communication clearly explaining the unproven nature and risks of the Cleared Device. Finally, the FDA should conduct an internal review of the process used to clear the Cleared Device, publish its findings, and refer the matter to the Office of Inspector General.

These actions are necessary until long-term oncologic safety and non-inferiority to conventional/open NSM have been established through complete clinical data (e.g., recurrence rates, disease-free survival, overall 10-year survival).

This petition builds directly on the earlier citizen petition filed by Harmed Americans for Reform in Medical-Device Safety Corp. in Docket FDA-2025-P-0439 (February 15, 2025) (attached as Exhibit 1), which requested evaluation of emerging studies on robotic-assisted mastectomy, restoration of the removed 2019 and 2021 safety communications, and updated guidance due to persistent oncologic evidence gaps. That petition correctly identified the ongoing lack of long-term oncologic data as a critical public health issue. The subsequent issuance of K252675 has exacerbated those concerns and warrants immediate agency action.

A. Action Requested

The undersigned request that the FDA:

1. Rescind or amend 510(k) clearance K252675 to immediately remove "nipple sparing mastectomy (NSM) procedures" from the Indications for Use statement, Professional Instructions for Use, and any related labeling of the da Vinci SP Surgical System, effective immediately and until oncologic safety and non-inferiority have been established via long-term data from appropriately powered, adjudicated, and completed trials.

2. Immediately restore to the FDA website (and make publicly available in full) the February 28, 2019, Safety Communication ("Caution When Using Robotically-Assisted Surgical Devices in Women's Health including Mastectomy and Other Cancer-Related Surgeries") and the August 20, 2021, update ("UPDATE: Caution with Robotically-Assisted Surgical Devices in Mastectomy").

3. Issue an updated guidance document or new safety communication reiterating that RAS devices lack established long-term oncologic safety/effectiveness for NSM in breast cancer treatment/prevention, caution against marketing/promotion/routine use pending such evidence, and impose post-market requirements if clearance is not revoked.

4. Conduct an expedited internal review of the Cleared Device (including any influence from former CDRH personnel), publish its findings, and refer the matter to the Office of Inspector General.

B. FDA Legal Authority to Act

The FDA has authority under the Federal Food, Drug, and Cosmetic Act (FD&C Act), Section 513 (21 U.S.C. § 360c), to rescind a clearance if there is evidence it was obtained by "fraud, ex parte contacts, or other misconduct tainting the original record and thereby affecting the integrity of an agency's proceedings." Ivy Sports Med., LLC v. Burwell, 767 F.3d 81, 88 (D.C. Cir. 2014). The FDA also has broad authority to regulate devices and device labels. 21 U.S.C. § 360(j). This includes requesting or mandating label changes and issuing public communications. It also has inherent authority to investigate itself to ensure it functions properly and is free from misconduct.

C. Statement of Grounds

Approximately 1 in 8 women will be diagnosed with breast cancer in her lifetime. Men also may, though less frequently than women, develop breast cancer. Many will have mastectomies

and prefer NSM. The Clearance wrongly suggests that the Cleared Device is safe and effective for robotic NSM. In fact, long-term oncological safety data do not exist. If healthcare providers adopt this device, women and men may unsuspectingly expose themselves to poorly understood cancer risks. This overarching concern is buttressed by the other grounds for our request:

1. *Inadequate Evidence for Oncologic Indications*. In surgical oncology, particularly for breast cancer, long-term cancer control outcomes are the definitive measure of safety and effectiveness. Short-term perioperative metrics (e.g., no conversions, comparable immediate complications, margin status) do not reliably predict long-term recurrence or survival—the very evidence gap the FDA identified in its 2019 and 2021 safety communications. Clearing the indication without oncologic data from completed trials prioritizes procedural equivalence over proven non-inferiority to conventional/open NSM, risking patient harm. Indeed, the clearance relied on bench/cadaver testing and short-term RCT data—not clinical oncologic outcomes. Review appears to have, inexplicably, prioritized perioperative surrogates over definitive oncologic endpoints.

2. *Inconsistency with Prior FDA Policy and Removed Warnings*. On February 28, 2019, the FDA issued a safety communication, which cautioned that RAS devices safety/effectiveness had not been established for mastectomy or cancer prevention/treatment, citing limited long-term oncologic outcomes and risks from analogous procedures. On August 20, 2021, the FDA issued another safety communication, which reiterated concerns and emphasized IDE requirements. Both were removed in 2024 without explanation, despite persistent gaps—as highlighted in Docket FDA-2025-P-0439. No data have been presented that assuage the concerns identified in these *Safety Communications.* For that reason, the FDA's K252675 clearance contradicts, without evidence, *the FDA's own warnings.* Curiously, it enables widespread adoption of a technology the agency itself warned had not been studied sufficiently.

3. *Bypass of Ongoing IDE Protections*. Because material oncologic concerns rendered the robotic NSM a significant-risk device, the FDA required Intuitive to conduct IDE-approved trials (e.g., NCT03892980 for RAS prophylactic NSM; NCT05720039/G220319, multicenter RCT for da Vinci SP NSM vs. open) prior to marketing. In particular, the Cleared Device lacks established long-term oncologic safety and effectiveness. The IDE framework exists to shield patients from broad exposure to investigational risks through controlled study conditions, informed consent, monitoring, and adverse event reporting until adequate evidence is available. It also ensures that firms have incentives to invest in clinical trials. Granting 510(k) clearance mid-trial—allowing routine commercial marketing and use outside those controls—undermines this core protective purpose and exposes breast cancer patients to an unproven oncologic indication based on inadequate surrogates. It also undermines incentives for firms to generate information, potentially misleading physicians into thinking it is safe and effective for its intended use.

4. *FDA Clearance Encouraging Medical Malpractice by Opening the Door to Breach of Standard-of-Care.* Robotic Nipple Sparing Mastectomy is not the current standard of care to treat patients with breast cancer. By clearing da Vinci robotic systems for that indication in the US, without any evidence of oncological safety, the FDA is encouraging practitioners to offer patients a nonstandard procedure/device that has unknown and potentially serious risks.

5. *Potential Conflicts.* Dr. William Maisel is the Vice President & Senior Medical Officer at Intuitive. Prior to his employment with Intuitive, Dr. Maisel was the Director of the Office of Product Evaluation and Quality (OPEQ), which had oversight of premarket reviews including those in OHT4. Given that Intuitive Surgical manufactures the Cleared Device, this raises questions about Dr. Maisel's potential influence at the FDA.

6. *Alignment with Prior Petition*. This request directly builds upon the concerns raised in Docket FDA-2025-P-0439 (February 15, 2025), which highlighted the persistent lack of long-term oncologic data for robotic-assisted mastectomy and called for restoration of the removed safety communications and updated guidance. The issuance of K252675 has intensified those issues and necessitates stronger action.

D. Summary of Actions Requested and Grounds

This petition seeks immediate corrective action by the FDA to address a significant regulatory discrepancy in the December 15, 2025, 510(k) clearance K252675 for the da Vinci SP Surgical System, which added "nipple sparing mastectomy (NSM) procedures" to the device's indications for use. The clearance was granted while a pivotal Investigational Device Exemption (IDE) trial (G220319 / NCT05720039) for the identical indication remains ongoing, with long-term oncologic follow-up incomplete. The clearance of K252675 undermines a key goal of this trial. It relies primarily on short-term perioperative data rather than long-term cancer outcomes (recurrence, disease-free survival, overall survival), directly contradicting the FDA's prior 2019 and 2021 safety communications and the protective intent of the IDE process.

E. Environmental Impact

Subject to Statutory Exemption

F. Economic Impact

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

G. Certification

The undersigned certify that, to their knowledge and belief, 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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EXHIBIT 1

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EXHIBIT A

Caution When Using Robotically-Assisted Surgical Devices in Women's Health including Mastectomy and Other Cancer-Related Surgeries: FDA Safety Communication

Date Issued

February 28, 2019

Audience

- People with breast cancer or those at high risk for breast cancer who are considering the surgical removal of one or both breasts (mastectomy) using robotically-assisted surgery
- People considering robotically-assisted surgery for the prevention or treatment of other cancers
- Health care providers who perform robotically-assisted procedures as part of cancer prevention or treatment
- Health care providers who advise patients on the need for mastectomy

Medical Specialties

Breast Surgery, Obstetrics and Gynecology, Gynecological Oncology, General Surgery, Surgical Oncology, Endocrine Surgery, Hepatobiliary Surgery, Thoracic Surgery, Urology, Colorectal Surgery, Medical Oncology, Radiation Oncology, Oncology Nurses, Primary Care.

Device

Robotically-assisted surgical devices enable surgeons to perform a variety of surgical procedures through small cuts (incisions) in a patient's body. This type of surgery may help reduce pain, blood loss, scarring, infection, and recovery time after surgery in comparison to traditional surgical procedures.

Computer and software technology allow a surgeon to precisely control surgical instruments attached to mechanical arms through small incisions while viewing the surgical site in three-dimensional high definition.

Purpose

The FDA takes women's health issues very seriously. The FDA is issuing this safety communication because it is important for health care providers and patients to understand that the safety and effectiveness of using robotically-assisted surgical devices in mastectomy procedures or in the prevention or treatment of cancer has not been established. There is limited, preliminary evidence that the use of robotically-assisted surgical devices for treatment or prevention of cancers that primarily (breast) or exclusively (cervical) affect women may be associated with diminished long-term survival. Health care providers and patients should consider the benefits, risks, and alternatives to robotically-assisted surgical procedures and consider this information to make informed treatment decisions.

Summary of Problem and Scope

Since robotically-assisted surgical devices became available in the US, robotically-assisted surgical procedures were widely adopted because they may allow for quicker recovery and could improve surgical precision. However, the FDA is concerned that health care providers and patients may not be aware that the safety and effectiveness of these devices has not been established for use in mastectomy procedures or the prevention or treatment of cancer. Patients and health care providers should also be aware that the FDA encourages health care providers who use robotically-assisted surgical devices to have specialized training and practice in their use.

Current evidence on use of robotically-assisted surgical devices

The safety and effectiveness of robotically-assisted surgical devices for use in mastectomy procedures or prevention or treatment of cancer has not been established. However, the FDA is aware of scientific literature and media publications describing surgeons and hospital systems that use robotically-assisted surgical devices for mastectomy.

To date, the FDA's evaluation of robotically-assisted surgical devices has generally focused on determining whether the complication rate at 30 days is clinically comparable to other surgical techniques. To evaluate robotically-assisted surgical devices for use in the prevention or treatment of cancer, including breast cancer, the FDA anticipates these uses would be supported by specific clinical outcomes, such as local cancer recurrence, disease-free survival, or overall survival at time periods much longer than 30 days.

The relative benefits and risks of surgery using robotically-assisted surgical devices compared to conventional surgical approaches in cancer treatment have not been established. The FDA is aware of peer-reviewed literature reporting clinical outcomes for the use of robotically-assisted surgical devices in cancer treatment including one limited report that compared long term survival after radical hysterectomy for cervical cancer either by open abdominal surgery or by minimally invasive surgery (which included laparoscopic surgery or robotically-assisted surgery). In this report minimally invasive surgery appeared to be associated with a lower rate of long term survival compared with open abdominal surgery; however other researchers have reported no statistically significant difference in long term survival when these types of surgical procedures are compared (*New England Journal of Medicine,* November 2018 (https://web.archive.org/web/20190724160505/https://www.nejm.org/doi/10.1056/NEJMoa1806395) (https://web.archive.org/web/20190724160505mp_/http://www.fda.gov/about-fda/website-policies/website-disclaimer)).

To date, the FDA has not granted marketing authorization for any robotically-assisted surgical device for use in the United States for the prevention or treatment of cancer, including breast cancer. The labeling for robotically-assisted surgical devices that are legally marketed in the United States includes statements that cancer treatment outcomes using the device have not been evaluated by the FDA.

Recommendations for Patients

Before you have robotically assisted surgery to prevent or treat cancer:

- Be aware that that the safety and effectiveness of using robotically-assisted surgical devices in mastectomy procedures or in the prevention or treatment of cancer has not been established.
- Discuss the benefits, risks, and alternatives of all available treatment options with your health care provider to make the most informed treatment decisions.

- Before choosing your surgeon, we recommend asking the following questions:
  - Ask your surgeon about his or her training, experience, and patient outcomes with robotically-assisted surgical device procedures.
  - Ask how many robotically-assisted surgical procedures like yours he or she has performed.
  - Ask your surgeon about possible complications and how often they happen.

If you had treatment with a robotically-assisted surgical device for any cancerous condition and experienced a complication, we encourage you to file a report through MedWatch, the FDA Safety Information and Adverse Event Reporting program (/web/20190724160505/https://www.fda.gov/safety/reporting-serious-problems-fda/reporting-health-professionals).

Recommendations for Health Care Providers

- Understand that the FDA has not cleared or approved any robotically-assisted surgical device based on cancer-related outcomes such as overall survival, recurrence, and disease-free survival.
- Be aware that robotically-assisted surgical devices have been evaluated by the FDA and cleared for use in certain types of surgical procedures, but not for mastectomy.
- The FDA recommends that you take training for the specific robotically-assisted surgical device procedures you perform.
- Talk to your patients about your experience and training, and the clinical outcomes expected with the use of robotically-assisted surgical devices.
- Discuss the benefits, risks, and alternatives of all available treatment options with your patients to help them make informed treatment decisions.
- Be aware that clinical studies conducted in the United States involving a legally marketed device investigating a new intended use are subject to FDA oversight. For further information, please refer to the FDA's Investigational Device Exemption website (/web/20190724160505/https://www.fda.gov/medical-devices/how-study-and-market-your-device/device-advice-investigational-device-exemption-ide).
- If any of your patients experience adverse effects or complications with a robotically-assisted surgical device, we encouraged you to file a report through MedWatch, the FDA Safety Information and Adverse Event Reporting program (/web/20190724160505/https://www.fda.gov/safety/reporting-serious-problems-fda/reporting-health-professionals).

FDA Actions

- Robotically-assisted surgical devices are novel and complex systems and the FDA reviews each robotically-assisted surgical device system individually, based on the complexity of the technology and its intended use.
- The FDA is monitoring adverse events in the literature and reported to the FDA to inform our understanding of the benefits and risks of robotically-assisted surgical devices when used for specific indications.
- The FDA encourages academic and research institutions, professional societies, robotically-assisted surgical device experts, and manufacturers to establish patient registries to gather data on the use of robotically-assisted surgical devices for all uses, including the prevention and treatment of cancer.

Patient registries may help characterize surgeon's learning curves, assess long-term clinical outcomes, and identify problems early to help enhance patient safety.

- The FDA will update this communication if significant new information becomes available.

Reporting Problems to the FDA

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with robotically-assisted surgical devices. If you experience adverse events associated with the use of these devices for treatment of cancerous conditions, we encourage you to file a voluntary report through MedWatch, the FDA Safety Information and Adverse Event Reporting program (/web/20190724160505/https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda). Health care personnel employed by facilities that are subject to the FDA's user facility reporting requirements (/web/20190724160505/https://www.fda.gov/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities) should follow the reporting procedures established by their facilities.

Other Resources

- New England Journal of Medicine: Minimally Invasive versus Abdominal Radical Hysterectomy for Cervical Cancer (https://web.archive.org/web/20190724160505/https://www.nejm.org/doi/full/10.1056/NEJMoa1806395) (https://web.archive.org/web/20190724160505mp_/http://www.fda.gov/about-fda/website-policies/website-disclaimer)
- CDRH Device Advice: Investigational Device Exemption (IDE) (/web/20190724160505/https://www.fda.gov/medical-devices/how-study-and-market-your-device/device-advice-investigational-device-exemption-ide)
- U.S. National Library of Medicine: ClinicalTrials.gov (https://web.archive.org/web/20190724160505/https://clinicaltrials.gov/)

Contact Information

If you have questions about this communication, please contact the Division of Industry and Consumer Education (DICE) at DICE@FDA.HHS.GOV (https://web.archive.org/web/20190724160505/mailto:DICE@FDA.HHS.GOV) (https://web.archive.org/web/20190724160505mp_/http://www.fda.gov/about-fda/website-policies/website-disclaimer), 800-638-2041 or 301-796-7100.

EXHIBIT B

UPDATE: Caution with Robotically-Assisted Surgical Devices in Mastectomy: FDA Safety Communication

Date Issued: August 20, 2021

The U.S. Food and Drug Administration (FDA) is reminding patients and health care providers that the safety and effectiveness of robotically-assisted surgical (RAS) devices for use in mastectomy procedures or in the prevention or treatment of breast cancer have not been established. In addition, the FDA is aware of allegations that clinical studies are being conducted using RAS devices to perform mastectomies for the prevention or treatment of cancer without the FDA oversight required for such significant risk studies.

RAS devices have been cleared for use in certain types of surgical procedures commonly performed in patients with cancer, such as hysterectomy, prostatectomy, and colectomy. These clearances are based on short-term (30 day) patient follow up. The FDA has not evaluated the safety or effectiveness of RAS devices for the prevention or treatment of cancer, based on cancer-related outcomes such as overall survival, recurrence, and disease-free survival.

The FDA continues to expect study sponsors to obtain FDA approval of investigational device exemptions (/web/20240118210655/https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/investigational-device-exemption-ide) (IDE) for studies of RAS devices intended for use in mastectomy procedures for the prevention or treatment of breast cancer. Studies with a potential for significant risk to study subjects, such as the use of RAS devices for mastectomy procedures or in the prevention or treatment of breast cancer, may only be conducted under an approved IDE. This helps assure adequate protections of the health, safety, and welfare of study subjects.

Recommendations for Patients and Caregivers

Before you have surgery to prevent or treat breast cancer, ask whether the surgeon expects to use robotically-assisted surgery. If so, you should:

- Be aware that the safety and effectiveness of using RAS devices in mastectomy procedures or in the prevention or treatment of breast cancer have not been established.
- Discuss the benefits, risks, and alternatives of all available treatment options with your health care provider to make the most informed treatment decisions.
- Before choosing a surgeon for robotically-assisted surgery, the FDA recommends you ask the surgeon about:
    - Their training, experience, and patient outcomes with RAS device procedures.
    - The number of robotically-assisted surgical procedures like yours they have performed.
    - Potential short-term and long-term complications, and whether they are due to the mastectomy procedure, cancer prevention, cancer treatment, or an associated breast reconstruction-and how often they happen.

If you had treatment with a RAS device for breast cancer or any cancerous condition and experienced a complication, the FDA encourages you to file a report through MedWatch, the FDA Safety Information and Adverse Event Reporting program (/web/20240118210655/https://www.fda.gov/safety/reporting-serious-problems-fda/reporting-health-professionals).

Recommendations for Health Care Providers

- Be aware that RAS devices have been evaluated by the FDA and cleared for use in certain types of surgical procedures, but not for mastectomy or for the prevention or treatment of breast cancer.
- The FDA recommends you get appropriate credentialing and training for the specific RAS device procedures you intend to perform.
- Talk to your patients about your experience and training as well as clinical outcomes expected with the use of RAS devices.
- Discuss the benefits, risks, and alternatives of all available treatment options with your patients to help them make informed treatment decisions.
- File a report through MedWatch, the FDA Safety Information and Adverse Event Reporting program (/web/20240118210655/https://www.fda.gov/safety/reporting-serious-problems-fda/reporting-health-professionals) if your patients experience adverse effects or complications with a RAS device.
- Be aware that clinical studies conducted in the United States involving a legally marketed device investigating a new intended use are subject to FDA oversight. For further information, please refer to the FDA's Investigational Device Exemption website (/web/20240118210655/https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/investigational-device-exemption-ide).

Recommendations for Institutional Review Boards (IRBs), Clinical Investigators, and Study Sponsors

The FDA considers clinical studies performed in the United States involving RAS devices for mastectomy and the prevention and treatment of cancer to be **significant risk studies**. These clinical studies require FDA oversight under an approved investigational device exemption.

- Be aware that clinical studies for mastectomy and for the prevention or treatment of breast cancer using RAS devices must include monitoring of long-term clinical outcomes, such as:
    - Cancer recurrence
    - Disease-free survival
    - Overall survival

In addition to long-term patient follow up, clinical studies for mastectomy and the prevention and treatment of breast cancer include safeguards such as study stopping rules and periodic reporting to the FDA. For further information, see Investigational Device Exemption (IDE) (/web/20240118210655/https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/investigational-device-exemption-ide).

- Be aware that studies of RAS devices intended for the prevention and treatment of other cancers also require an IDE.
- The FDA recommends the development of RAS surgery device registries for the collection of real-world evidence (/web/20240118210655/https://www.fda.gov/science-research/science-and-research-special-topics/real-world-evidence). Please contact the FDA for information on whether your RAS device registry requires Investigational Device Exemption through the pre-submission (Q-Sub) program (/web/20240118210655/https://www.fda.gov/media/114034/download?attachment).

Device Description

RAS devices enable surgeons to perform a variety of surgical procedures through small cuts (incisions) in a patient's body. This type of surgery may help reduce pain, blood loss, scarring, infection, and recovery time after surgery in comparison to traditional surgical procedures.

Computer and software technology enable a surgeon to precisely control surgical instruments attached to mechanical arms through small incisions while viewing the surgical site in three-dimensional high definition.

For more information, see the Common uses of Robotically-Assisted Surgical (RAS) Devices (https://web.archive.org/web/20240118210655/https://www.fda.gov/medical-devices/surgery-devices/computer-assisted-surgical-systems#2) section on the Computer-Assisted Surgical Systems page.

Concerns about Safety and Effectiveness of RAS Devices in Cancer Prevention or Treatment

While robotically-assisted surgery is an important treatment option that is safe and effective when used appropriately and with proper training, the FDA has not granted marketing authorization for any RAS device system for use in the United States specifically for the prevention or treatment of cancer.

There is little evidence on the safety and effectiveness of the use of RAS devices in patients undergoing mastectomy for the prevention or treatment of breast cancer, and the FDA has not granted any RAS system marketing authorization for mastectomy. For patients undergoing mastectomy, the surgical approach used with RAS devices differs from conventional surgical approaches. The impact of these differences on prevention of cancer, overall survival, recurrence, and disease-free survival have not been established.

FDA Actions

The FDA is working to assure device manufacturers, investigators, clinical study sponsors, and IRBs are aware of the FDA's expectations for an investigational device exemption and clinical endpoints for use of RAS devices for the prevention or treatment of patients with cancer.

The FDA continues to monitor adverse events reported to the FDA to inform our understanding of the benefits and risks of RAS devices when used for specific indications.

The FDA continues to encourage academic and research institutions, professional societies, RAS device experts, and manufacturers to establish patient registries to gather data on the use of RAS devices for all uses, including the prevention and treatment of cancer.

The FDA will keep the public informed if significant new information becomes available.

Reporting Problems with Your Device

If you think you had a problem with your device, the FDA encourages you to report the problem through the MedWatch Voluntary Reporting Form (https://web.archive.org/web/20240118210655/https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home).

Health care personnel employed by facilities that are subject to the FDA's user facility reporting requirements should follow the reporting procedures established by their facilities.

Questions?

If you have questions, email the Division of Industry and Consumer Education (DICE) at DICE@FDA.HHS.GOV (https://web.archive.org/web/20240118210655/mailto:DICE@FDA.HHS.GOV) (https://web.archive.org/web/20240118210655mp_/https://web.archive.org/about-fda/website-policies/website-disclaimer) or call 800-638-2041 or 301-796-7100.