March 2, 2026

VIA ELECTRONIC FILING
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 Investigate Mayo Clinic Promotion and Use of Robotic Nipple-Sparing Mastectomy Using the da Vinci SP Surgical System Outside the Ongoing Investigational Device Exemption; Investigate Intuitive Surgical's Role in this Promotion; Reevaluate Clearance of da Vinci SP Surgical System for Robotic Nipple-Sparing Mastectomy (K252675); Require Post-Market Surveillance/Labeling Changes; and Communicate with CMS to Clarify IDE Status of Robotic Mastectomy and Reimbursement Implications

The undersigned submit this petition under 21 C.F.R. §§ 10.20, 10.25, 10.30, and the Administrative Procedure Act to request immediate action relating to Mayo Clinic's promotion and use of the robotic nipple-sparing mastectomy ("NSM") using the da Vinci SP Surgical System ("da Vinci"), which the FDA recently cleared (K252675) on December 15, 2025.

A. Action Requested

The undersigned request that the FDA:

1. Investigate Mayo Clinic ("Mayo") and Intuitive Surgical, Inc. ("Intuitive") for possible violations of the Investigational Device Exemption ("IDE") regulations related to ongoing IDE clinical trial NCT05720039 / G220319.

2. Investigate Mayo and Intuitive for possible misbranding and adulteration violations.

3. Reevaluate its decision to clear through Premarket Notification the da Vinci SP Surgical System ("da Vinci") for robotic Nipple-Sparing Mastectomy ("NSM"), K252675 ("the Clearance").

4. Require Intuitive to place a warning on the da Vinci that clearly states there are no long-term data that support oncologic safety and effectiveness for NSM.

5. Impose post-market requirements on Intuitive (and referencing providers like Mayo) for enhanced surveillance of oncologic outcomes in cleared NSM uses, in addition to completing the IDE with the full sample size as initially planned.

6. Promptly communicate with CMS and clearly state that the Clearance does not affect CMS's reimbursement regulations for open IDEs.

B. FDA Legal Authority to Act

FDA has broad authority under the Food, Drug, and Cosmetic Act (FDCA) to regulate devices, including promotion and labeling.[1]

1. *Adulteration and Misbranding*

A device is misbranded when "its labeling is false or misleading in any particular."[2] The labeling must bear "(1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users."[3] The labeling must provide "directions under which the layman can use a device safely and for the purposes for which it is intended."[4]

For prescription devices, labeling must contain "adequate information for such use, including indications, effects, routes, methods, and frequency and duration of administration and any relevant hazards, contraindications, side effects, and precautions, under which practitioners licensed by law to employ the device can use the device safely and for the purposes for which it is intended, including all purposes for which it is advertised or represented."[5] Federal regulations also state that "any representation that creates an impression of official approval of a device because of complying with the premarket notification regulations is misleading and constitutes misbranding." In other words, misbranding occurs when a 510(k)-cleared device is advertised or promoted as FDA-approved.[6] Additionally, dissemination "of information relating to a new use for a drug or device may constitute labeling, evidence of a new intended use, adulteration, or misbranding of the . . . device . . . ."[7]

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[1] 21 U.S.C. § 301 *et seq.*

[2] 21 U.S.C. § 352(a)

[3] 21 U.S.C. § 352(f).

[4] 21 C.F.R. § 801.5.

[5] 21 C.F.R. § 810.109(d).

[6] 21 C.F.R. § 807.97.

[7] 21 C.F.R. § 99.405.

2. *Nonmanufacturer Misbranding and Adulteration*

Although the FDCA typically applies to manufacturers, it is not limited to them. For example, the FDCA prohibits "[t]he adulteration or misbranding of any food, drug, device, tobacco product, or cosmetic in interstate commerce," or "*the causing thereof*."[8] In other words, non-manufacturers or distributors can also violate the FDCA when they possess a device but do not manufacture it.[9] For instance, the FDA has recently issued warning letters to online retailers offering compounded drugs in ways that rendered them misbranded.[10] Likewise, those offering devices for procedures may also adulterate or misbrand a device by modifying the labeling in ways that violate the FDCA.

Misbranding also occurs upon "[t]he alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a . . . device . . . if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded."[11] Courts have found that a physician or hospital has "held for sale" a device once it receives it and intends to use it on patients.[12] Providing marketing materials about the device can also constitute an act "with respect to" a device. As one court noted, "the potentiality of harm to the public from misbranded drugs is not less because the intervening agency of distribution may be a physician rather than a layman."[13]

3. *Investigational Device Exemption*

Some devices, however, may be exempt from certain portions of the FDCA, including misbranding provisions, for a clearly identified reason.[14] One type of device is a "significant risk

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[8] 21 U.S.C. § 1331(b) (emphasis added).

[9] *See* David A. Simon, *Off-Label Speech*, 72 EMORY L. J. 549 (2023).

[10] E.g., U.S. Food & Drug Admin., Warning Letter to Sprout Health Partners LLC d/b/a Sprout Health (Sept. 9, 2025), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/sprout-health-partners-llc-dba-sprout-health-09092025.

[11] 21 U.S.C. § 331(k).

[12] 21 U.S.C. § 331(k). United States v. Kaplan, 836 F.3d 1199 (9th Cir. 2016).; United States v. 10 Cartons, Etc., 152 F. Supp. 360 (W.D. Pa. 1957) (applying held for sale provision to printed materials distributed with drugs).

[13] United States v. 10 Cartons, Etc., 152 F. Supp. 360 (W.D. Pa. 1957).

[14] 21 C.F.R. § 812.1 (exempt from "Misbranding under section 502 of the act, registration, listing, and premarket notification under section 510, performance standards under section 514, premarket approval under section 515, a banned device regulation under section 516, records and reports under section 519, restricted device requirements under section 520(e), good manufacturing practice requirements under section 520(f) except for the requirements found in § 820.10(c), if applicable (unless the sponsor states an intention to comply with these requirements under § 812.20(b)(3) or § 812.140(b)(4)(v)) and color additive requirements under section 721.").

device" that sponsors and investigators can study under strict federally regulated clinical conditions.[15] To facilitate this process, the FDA has created the investigational device exemption (IDE). To qualify for the IDE, the sponsor of an investigation of a significant risk device must apply for and receive FDA approval.[16] A "significant risk device" is one that

> . . . [i]s for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or
>
> . . . Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.[17]

These definitions speak to the nature of the harm presented by the device. More serious harms and adverse events are more likely to make a device a substantial risk device that requires an IDE.

Because significant risk devices involve serious risks to patient health, the FDA mandates that investigators submit an application to the agency[18] and comply with rules on, among other things, labeling,[19] promotion,[20] trial design,[21] reporting,[22] institutional review board requirements,[23] and data privacy.[24] In effect, the IDE regulation has its own misbranding regulations. For instance, "[t]he labeling of an investigational device shall not bear any statement that is false or misleading in any particular and shall not represent that the device is safe or effective for the purposes for which it is being investigated."[25]

IDE regulations also cover promotional activities. They state that "[a] sponsor, investigator, or any person acting on behalf of the sponsor or investigator shall not:

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[15] 21 C.F.R. § 812.1

[16] 21 C.F.R. § 812.

[17] 21 C.F.R. § 812.3(m).

[18] 21 C.F.R. § 812.20(a)(1)-(2).

[19] 21 C.F.R. § 8212.5.

[20] 21 C.F.R. § 812.7.

[21] 21 C.F.R. § 812.25.

[22] 21 C.F.R. § 812.27.

[23] 21 C.F.R. § 812.60-66.

[24] 21 C.F.R. § 812.38.

[25] 21 C.F.R. § 812.15(b).

> (a) Promote or test market an investigational device, until after FDA has ***approved*** the device for commercial distribution.
>
> . . . .
>
> (d) Represent that an investigational device is safe or effective for the purposes ***for which it is being investigated***."[26]

These prohibitions are crucial components of the IDE framework. The first (21 C.F.R. § 812.7(a)) ensures that firms do not use the IDE pathways as a loophole to marketing authorization. Before they can "promote or test market" the device subject to the IDE, they must obtain FDA premarket *approval* (not 510(k) clearance).[27] This also incentivizes firms to file a PMA when the trial is complete. The second (21 C.F.R. § 812.7(d)) prevents firms from representing that the device is safe and effective for the precise indication that is subject to the IDE. Like the first provision, this one prevents misleading marketing to consumers and physicians. And it also ensures that firms continue to study the device for its safety and effectiveness for the entire duration of the IDE trial period.

In short, the IDE pathway is not an exception to typical market requirements. It is a clearly defined, risk-based approach to study a new use of devices to gather safety and effectiveness data in ways that promote scientific progress and reduce patient harm. And its mandate is clear: if you want to study a significant risk device, you cannot do so unless the FDA approves your IDE application. And once you have an IDE, you cannot promote or market your device for the studied use unless and until the IDE study is complete and the FDA has granted premarket approval for the device (and its studied indication). The entire IDE framework assumes that significant risk devices require full safety and effectiveness demonstration before commercial promotion. If FDA can clear the exact investigational indication mid-trial under 510(k), § 812.7 becomes meaningless.

4. *FDA Authority*

The FDA has authority under the FDCA to issue warnings and public communications, conduct investigations and inspections, regulate and enforce IDE trial requirements, and mandate post-market studies and surveillance. The FDA and CMS also have a Memorandum of Understanding for IDEs that enable coordination.[28] The FDA also has the authority to

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[26] 21 C.F.R. § 812.7(a), (d).

[27] The FDA is familiar with its own regulatory pathways, and is careful to emphasize the difference between approval, clearance, and other forms of authorization. By using the word "approved," the FDA clearly intended to require a PMA for significant risk IDEs.

[28] Memorandum of Understanding Between the Centers for Medicare & Medicaid Services Coverage and Analysis Group and the U.S. Food and Drug Administration Center for Devices and Radiological Health Regarding Categorization of Investigational Devices, MOU 225-16-004 (Dec. 1–2, 2015), at U.S. Food & Drug Admin., https://www.fda.gov/about-fda/domestic-mous/mou-225-16-004 (last updated Dec. 18, 2017).

require manufacturers of a Class II device, either before or after authorization, to conduct postmarket surveillance when "the failure of [the device] would be reasonably likely to have serious adverse health consequences . . . ."[29]

C. Statement of Grounds

This section explains the reasons for the requests in this Petition. First, it describes how Mayo may have violated the IDE regulation that carefully protects patients and research integrity. Second, it shows that, even if the IDE regulations don't apply, Intuitive may have violated the FDCA. Third, it explains that the FDA's decision to issue the Clearance (labeling modification for the da Vinci adding "nipple sparing mastectomy (NSM) procedures" based on short-term equivalence) was arbitrary and capricious, and should be revisited. Fourth, it requests that the FDA put a cancer-risk warning on the da Vinci label stating that there are no long-term data that support oncologic safety and effectiveness for NSM. Fifth, it requests that the FDA order Intuitive to conduct postmarket studies on oncologic safety. Sixth, it requests FDA communicate with CMS about, and clarify for providers, the reimbursement status of robotic NSM given the open IDE.

1. FDA Action on Mayo Promotion and Representation

On April 20, 2023, Intuitive received an IDE approval from CMS to study "Robotic vs. Open NSM for Early Stage Breast Cancer (SP NSM)."[30] That trial has an estimated 204 patients to be enrolled and is still open, though no longer recruiting despite not having enrolled the planned number of subjects. And is not scheduled to be completed until March 2031. Mayo operates two of the sites participating in the IDE trial.

Despite the ongoing IDE clinical trial, Mayo Clinic has begun marketing the da Vinci SP Surgical System (SP1098) for robotic NSM. For example, Mayo's January 30, 2026, press release initially advertised robotic NSM as "newly FDA-approved." After it was pointed out that the device is *not* approved for robotic NSM,[31] Mayo revised its press release to state the device "received clearance":

Image 1. New Disclaimer on Press Release[32]

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[29] 21 U.S.C. § 360l(a)(1)(A)(i), (iii).

[30] Although the FDA IDE-approval is not public, it is a precondition the approved CMS IDE. IDE No. G220319, NCT No. NCT05720039, CMS Approval Date (April 20, 2023), https://clinicaltrials.gov/study/NCT05245812.

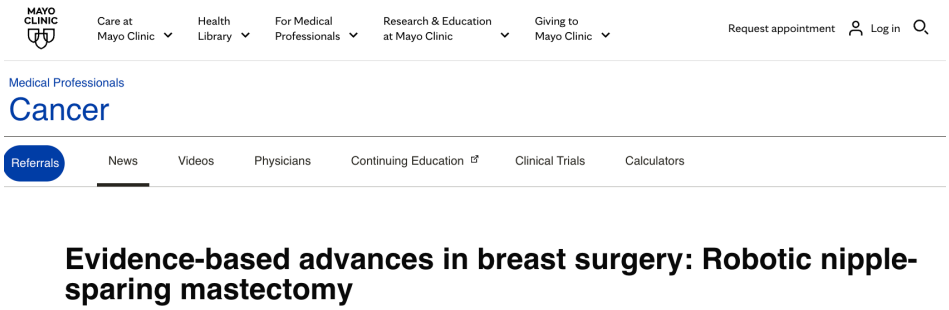
[31] Hooman Noorchashm, *Mayo Clinic's Claim of "FDA-Approved" Robotic Nipple-Sparing Mastectomy*, Medium (Feb. 20, 2026), https://noorchashm.medium.com/mayo-clinics-claim-of-fda-approved-robotic-nipple-sparing-mastectomy-false-advertising-and-770e6329fb11.

[32] Evidence-based Advances in Breast Surgery: Robotic Nipple-Sparing Mastectomy, Mayo Clinic Comprehensive Cancer Center (Feb. 19, 2026), https://www.mayoclinic.org/medical-

Editorial note: *This article has been updated to reflect that the robotic device has received clearance by the U.S. Food and Drug Administration for certain indications, including the use described in the article.*

Despite this welcome revision, Mayo still frames robotic NSM as a routine "evidence-based advance":

Image 2. Headline from Mayo Press Release[33]



The press release does not contain disclaimers on the lack of long-term oncologic safety/non-inferiority. It does not discuss the existence of an ongoing IDE clinical trial focused on studying this exact indication, in which Mayo is a participating center. Nor does it explain what makes the procedure "evidence based."

There are two aspects of Mayo's press releases and subsequent promotion of the da Vinci for robotic NSM that are problematic, potentially unlawful, and require proper regulation from the FDA.

a. Possible Violation of the IDE

The first involves possible violations of the IDE regulation. IDE regulations apply to Mayo because it was an "investigator, or . . . person acting on behalf of the sponsor." As a result, Mayo must comply with all components of the IDE regulations, which clearly prohibit the device's labeling from representing "that a device is safe or effective for the purposes for which it is being investigated."[34] Labeling is construed broadly to include any written materials that accompany the device.[35]

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professionals/cancer/news/evidence-based-advances-in-breast-surgery-robotic-nipple-sparing-mastectomy/mac-20595607.

[33] *Id.*

[34] 21 C.F.R. § 812.7(d).

[35] 21 U.S.C. § 321(m); 21 C.F.R. § 1.3.

Here the da Vinci device is being investigated *specifically for oncological safety in robotic NSM*. Yet Mayo is touting the da Vinci robotic NSM, claiming it is "evidence-based" and "FDA approved" when the device is still under an active IDE. It has stated that this "approach is ideal for patients with smaller cancers located away from the nipple and skin, as well as individuals at increased risk of breast cancer who are considering prophylactic mastectomy."[36] All of this suggests the da Vinci is safe and effective for mastectomy, which is the precise condition under investigation.

Additionally, the IDE regulations prohibit promotion and test marketing of a device "until after the FDA has approved" it.[37] Here, neither Intuitive nor Mayo obtained approval for the da Vinci NSM. Instead, Intuitive secured a *clearance* of the device. The point of the IDE is to generate safety and effectiveness information to support approval, not clearance. Devices cleared with clinical testing are often non-significant risk devices that rely on non-FDA-approved IDE/IRBs.[38] Moreover, even if the FDA has previously cleared devices based on IDE data, it violated the law and should not do so in the future—and it certainly should not do so *before the IDE study is complete*.

Perhaps most importantly, if the IDE study is still ongoing, the sponsor or investigator cannot "represent the device is safe and effective for the purposes for which it is being investigated."[39] Here Mayo has repeatedly touted robotic NSM as "evidence-based" and "FDA approved" when the device is still under an active IDE. It has stated that "approach is ideal for patients with smaller cancers located away from the nipple and skin, as well as individuals at increased risk of breast cancer who are considering prophylactic mastectomy." The fact that the FDA has cleared the device does not absolve the sponsors or investigators of their obligations under the IDE. How could it? The Clearance was based on limited data that did not and could not possibly show the long-term oncological safety and non-inferiority of the device to the existing standard open mastectomy approach to breast cancer.[40]

Attention to Mayo's activities is crucial given it has already attempted to silence protected speech directed against its questionable promotional activity.[41] Although it did modify its press

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[36] Evidence-based Advances in Breast Surgery: Robotic Nipple-Sparing Mastectomy, Mayo Clinic Comprehensive Cancer Center (Feb. 19, 2026), https://www.mayoclinic.org/medical-professionals/cancer/news/evidence-based-advances-in-breast-surgery-robotic-nipple-sparing-mastectomy/mac-20595607.

[37] 21 C.F.R. § 812.7(a).

[38] Premarket Notification (510(k)) K970367 for Thermo-STAT System (Dec. 17, 1997), U.S. Food & Drug Admin., https://www.accessdata.fda.gov/cdrh_docs/pdf/K970367.pdf. These are often referred to as "abbreviated IDEs" because they do not require FDA approval and instead rely on IRB review. Even abbreviated IDEs, however, are regulated by the FDA.

[39] 21 C.F.R. § 812.7(d).

[40] FDA-2026-P-1819.

[41] See Cease and Desist Letter, Ropes & Gray to Hooman Noorchashm, Feb. 25, 2026, attached as Exhibit A.

release to reflect FDA clearance instead of approval, it also attempted to suppress criticism of its marketing and promotion.[42] FDA action is crucial to ensuring that Goliath firms, like Mayo and Intuitive, do not use their resources to bully criticism from David out of existence.

b. Possible Misbranding and Adulteration

Assuming for the sake of argument that there are no IDE violations, the FDA should investigate whether Mayo or Intuitive violated the misbranding and adulteration provisions of the FDCA. If Intuitive induced or directed Mayo's advertising, it can be responsible for any violations arising from it.

The FDCA's provisions do not apply only to device manufacturers, but also to any person who "causes" adulteration or misbranding. Likewise, Mayo has certainly "held for sale" the da Vinci, as it uses it frequently to operate on patients, including, by its own promotion, for robotic NSM. Mayo's statements about the da Vinci device and the evidence supporting its safety and effectiveness may alter the labeling of the device—they are also likely an act "with respect to the device." And Mayo's statements that robotic NSM is FDA-approved when it was only cleared through the 510(k) pathway "create[d] an impression of official approval of a device because of complying with the premarket notification regulations . . . ."[43] All of these are sufficient for the FDA to investigate possible misbranding and adulteration violations.

Intuitive's relationship with Mayo is not clear. But some information is known. Intuitive sponsored the IDE trial in which Mayo is a participant. Separately, Intuitive has provided more than $1 million in payments to Mayo.[44] At least one of the surgical oncologists involved with the Mayo advertising is also a paid KOL/Consultant to Intuitive. Mayo also touts the da Vinci robot in various marketing materials. If Intuitive has in some way directed Mayo's activities, it may be responsible for FDCA violations.

2. FDA's Action is Arbitrary and Capricious

The FDA's action to clear the da Vinci for the indication of robotic NSM is arbitrary and capricious.[45] As described in our earlier petition, the decision is not supported by sufficient evidence.[46] More than that, however, the decision undermines the ongoing IDE trial, the purpose of which is to generate sufficient long-term oncologic data. The IDE also is designed to produce data for significant risk devices that supports a PMA, not a 510(k)—and certainly not before the IDE trial is completed. To appropriately and safely expand the da Vinci label for patients with cancer, Intuitive should seek a PMA *but only after* it has fully completed the

[42] *Id.*

[43] 21 C.F.R. § 807.97.

[44] Data Source: Open Payments. Mayo Rochester, MN ($1,061,484.19).

[45] 5 U.S.C. § 706.

[46] FDA-2026-P-1819.

original IDE trial *and* the evidence establishes da Vinci non-inferiority to the established standard of care for long-term oncological outcomes. By short-circuiting the IDE trial and discarding statutory language, the FDA has acted in an arbitrary and capricious manner. In other words, by clearing the exact indication that is the subject of a significant risk IDE clinical trial, the FDA has either disregarded the statutory language or reinterpreted it without explanation.

3. FDA Should Amend the Clearance

Even if FDA did not exceed its authority in granting the clearance, it should amend it to reflect the existing evidence. There is no long-term safety data for the da Vinci robotic NSM. FDA should revise the 510(k) to remove clearance for robotic NSM. Alternatively, to ensure physicians, hospitals, and patients are adequately informed, the FDA could require Intuitive to place the following warning on its label:

"The oncologic safety of robotic NSM has not been established."

4. FDA Should Require Postmarketing Studies

The FDA should order Intuitive to conduct postmarket surveillance, *in addition to completing the IDE clinical trial*. The preliminary data relied on do not provide robust evidence of oncologic safety and effectiveness. There are still serious questions about what the long-term consequences of this procedure will be for cancer patients. At a minimum, FDA should mandate additional robotic NSM data collection and device registries.

5. FDA Should Coordinate with CMS

Although CMS is responsible for IDE approval and payment of claims under the IDE trial, FDA can coordinate with CMS about IDE decisions. CMS has already approved the IDE for use of the da Vinci in robotic NSM as a category B device. This means that CMS will pay for the da Vinci only as part of the IDE trial. FDA's recent decision to clear da Vinci for Robotic NSM undermines the payment structure of CMS, which by law it is obligated to follow. Because of FDA's decision, clinics like Mayo may incorrectly assume that it is legal to bill CMS for use of the da Vinci in robotic NSM in ordinary care. FDA should clarify that its decision is separate and independent from CMS and has no effect on CMS's payment decisions under the IDE.

D. Summary of Actions Requested and Grounds

For all the reasons stated, the undersigned request that the FDA:

1. Investigate Mayo Clinic ("Mayo") and Intuitive Surgical, Inc. ("Intuitive") for possible violations of the Investigational Device Exemption ("IDE") regulations related to ongoing IDE clinical trial NCT05720039 / G220319.

2. Investigate Mayo and Intuitive for possible misbranding and adulteration violations.

3. Reevaluate its decision to clear through Premarket Notification the da Vinci SP Surgical System ("da Vinci") for robotic Nipple-Sparing Mastectomy ("NSM"), K252675 ("the Clearance").

4. Require Intuitive to place a warning on the da Vinci that clearly states there are no long-term data that support oncologic safety and effectiveness for NSM.

5. Impose post-market requirements on Intuitive (and referencing providers like Mayo) for enhanced surveillance of oncologic outcomes in cleared NSM uses, in addition to completing the IDE with the full sample size as initially planned.

6. Promptly communicate with CMS and clearly state that the Clearance does not affect CMS's reimbursement regulations for open IDEs.

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 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
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/s/ Michael K. Paasche-Orlow
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Exhibit A
Cease & Desist Letter from Ropes & Gray

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February 25, 2026

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BY E-MAIL

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Re: Allegations Regarding Mayo Clinic's Press Release Related to Robotic Nipple-Sparing Mastectomy Treatment

Dear Dr. Noorchashm:

We are writing on behalf of our client, Mayo Clinic (hereafter referred to as "Mayo"), in regard to various communications—including multiple articles[1] you have published on the Medium social publishing platform; posts you have made on social media, including X[2]; and emails you have sent to various individuals, including personnel from Mayo[3]—making allegations related to a Mayo press release regarding robotic nipple-sparing mastectomy ("NSM") treatment using the da Vinci SP Surgical System (hereafter referred to as the "da Vinci System"). As described below, your allegations are wholly without merit and are based on fundamental misunderstandings of law and fact. We hereby

[1] *See, e.g.,* Hooman Noorchashm, *URGENT PATIENT SAFETY WARNING TO MAYO CLINIC'S DR. MICHAEL L. KENDRICK – Your Department's Dangerous, Unlawful Promotion and Routine Use of Investigational Robotic Nipple-Sparing Mastectomy*, MEDIUM.COM, *available at* https://noorchashm.medium.com/urgent-patient-safety-warning-to-mayo-clinics-dr-f36b6c720d70 (last accessed Feb. 25, 2026) (hereafter referred to as the "Patient Safety Warning Article"); Hooman Noorchashm, *Mayo Clinic's Claim of "FDA-Approved" Robotic Nipple-Sparing Mastectomy: False Advertising and Promotion of an Investigational Procedure Outside Standard of Care*, MEDIUM.COM, *available at* https://noorchashm.medium.com/mayo-clinics-claim-of-fda-approved-robotic-nipple-sparing-mastectomy-false-advertising-and-770e6329fb11 (last accessed Feb. 25, 2026) (hereafter referred to as the "Robotic NSM False Advertising Article").

[2] *See, e.g.,* Hooman Noorchashm MD, PhD (@HoomNoorchashm), X (Feb. 22, 2026, 2:31PM EST), https://x.com/hoomnoorchashm/status/2025654815708037616?s=46 (". . . Mayo Clinic is engaged in a misbranding violation under the Food, Drug and Cosmetics Act, in collaboration with @IntuitiveSurg and its executives, including William Maisel and Myriam Curet, MD, FACS. This violation has, almost certainly, been facilitated by Mark Trumbore and Heather Agler at @FDAcdrhIndustry").

[3] In addition to Mayo personnel, you have also reiterated these allegations in email correspondence directed to personnel from Intuitive Surgical (hereafter referred to as "Intuitive"), Tufts Medical Center, Northeastern University, the U.S. Food and Drug Administration (hereafter referred to as the "FDA"), the Wall Street Journal, the New York Times, and Bloomberg News.

demand that you (1) withdraw the publications posted on Medium; (2) cease further dissemination of your false allegations through social media or any other communication media; and (3) cease all unsolicited communications with Mayo personnel regarding this matter.

Mayo is the largest integrated, not-for-profit medical group practice in the world. Mayo is committed to providing the highest level of care to patients, whether in the research or clinical setting, to prioritizing patient safety, and to adhering to all legal and ethical obligations. In your communications, you make various allegations regarding a press release issued by Mayo about the availability of NSM treatment. Specifically, you allege that Mayo:

(a) is engaged in false advertising that constitutes a misbranding violation under the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 331 *et seq.*;[4]

(b) may have engaged in the submission of false claims to insurers, including the Centers for Medicare & Medicaid Services ("CMS"), in violation of the False Claims Act, 31 U.S.C. §§ 3729-3733;[5] and

(c) is actively promoting medical malpractice and compromising patient safety, including by undermining informed consent for patients undergoing robotic NSM treatment.[6]

Mayo vehemently denies these allegations, which are inflammatory in nature and are based on material misunderstandings of both the law and the facts at issue.

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[4] *See, e.g.,* Patient Safety Warning Article ("Your institution's January 30, 2026, press release originally advertised the procedure falsely as 'newly FDA-approved' — a clear misbranding violation under the Federal Food, Drug, and Cosmetic Act . . . Following my prior alerts and analysis, the release was updated to reference "clearance" with an editorial note acknowledging the change — but this does not remedy the fundamental issue: ongoing promotion and non-trial offering of a significant-risk investigational procedure without transparent disclaimers about its unknown long-term oncologic risks"); *see also* Robotic NSM False Advertising Article ("***Post-publication Addendum****: Following publication of this article, the Mayo clinic revised its press release and eliminated its false claim that robotic mastectomy is 'FDA-Approved'. The title of that press release now reads 'Evidence-based advances in breast surgery at Mayo Clinic: Robotic nipple-sparing mastectomy'. Though this change has eliminated the 'FDA-approved' language, it remains false given than the evidence for the oncological safety of robotic mastectomy will not be available and complete until 2030. Therefore, the Mayo Clinic remains in legal violation of the FDCA for false advertising and a misbranding violation*").

[5] *See, e.g.,* Patient Safety Warning Article ("Billing insurers (including federal programs) for these as standard rather than investigational procedures risks substantial False Claims Act liability"); *see also* Robotic NSM False Advertising Article ("By publicly advertising robotic mastectomy outside the IDE trial, Mayo Clinic is encouraging surgeons to perform — and bill for — an investigational procedure as if it were established therapy. This raises the very real prospect of false claims being submitted to CMS (Centers for Medicare & Medicaid Services) for any Medicare/Medicaid patients undergoing robotic NSM outside the approved IDE protocol").

[6] *See, e.g.,* Patient Safety Warning Article ("Inadequate disclosure of the investigational status and uncertain oncologic safety violates informed consent principles and deviates from the standard of care — exposing surgeons to malpractice exposure"); *see also* Robotic NSM False Advertising Article ("By falsely advertising robotic NSM as 'FDA-approved' and routinely available for breast cancer treatment, Mayo Clinic is actively promoting medical malpractice and compromising patient safety . . . Falsely claiming 'FDA approval' vitiates informed consent: patients cannot make truly informed decisions when presented with inaccurate regulatory and evidence information").

As an initial matter, in alleging that Mayo is engaged in misbranding under the FDCA, you fail to recognize that the FDCA's provisions and implementing regulations regarding misbranding and false and misleading labeling apply to medical device manufacturers and those acting on their behalf.[7] Mayo is neither.

Additionally, each allegation is founded on a fundamental misconception regarding FDA's processes for granting premarket authorization to medical devices. As acknowledged in your communications, the da Vinci System received 510(k) clearance on December 15, 2025, specifically for use in NSM procedures.[8] Your characterization of 510(k) clearance as meaning something other than that FDA has determined that a device is safe or effective for its intended use[9] represents, at best, a misleading interpretation of FDA's medical device regulatory framework.

The FDCA has established multiple pathways by which medical devices may be granted authorization to be introduced into interstate commerce, including both the 510(k) clearance and PMA pathways. As FDA explicitly acknowledges, while the review standards between the 510(k) and PMA pathways differ,[10] "the principles of safety and effectiveness underlie the substantial equivalence determination in every 510(k) review."[11,12] FDA goes on to explain that, in the case of both PMAs and 510(k) clearances, FDA's review reflects the agency's determination of the level of regulatory control necessary to provide a "reasonable assurance of safety and effectiveness" and that, in the 510(k) context, FDA generally relies, in part, on FDA's prior determination that a reasonable assurance of safety and effectiveness exists for the predicate device to which the new device is being compared.[13] Regardless of your personal view on the sufficiency of the existing evidence of safety and effectiveness for the da Vinci System in robotic NSM treatment, FDA's 510(k) clearance permits the system's manufacturer to commercialize the system for this use—meaning, *inter alia*, that use of the device for NSM need not occur pursuant to a research protocol. Mayo's press release and related activities are therefore completely appropriate.[14]

You also assert throughout your communications that robotic NSM is an "investigational" procedure, citing the existence of clinical trial NCT05720039 (hereafter referred to as the "IDE Study"), sponsored by Intuitive. You further assert that Mayo's promotion of, provision of, and billing for

[7] *See, e.g.*, 21 C.F.R. § 801.4, 801.109(d).
[8] *See* K252675, *available at* https://www.accessdata.fda.gov/cdrh_docs/pdf25/K252675.pdf (last accessed Feb. 25, 2026).
[9] *Id.*
[10] In explaining the functional distinction between the review standards, FDA explains that "[t]he 510(k) review standard is comparative, whereas the PMA standard relies on an independent demonstration of safety and effectiveness." *See* FDA, Guidance for Industry and Food and Drug Administration Staff – The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications (July 28, 2014) at 6, *available at* https://www.fda.gov/media/82395/download (last accessed Feb. 25, 2026) (hereafter referred to as the "510(k) Guidance").
[11] As you are aware, Mayo's initial references to the device as FDA-approved, rather than FDA-cleared, have been updated. Neither the distinction between the 510(k) and PMA regulatory pathways, nor the corresponding updates made by Mayo, in any way support an allegation that the use of the da Vinci system for NSM is unsafe or ineffective.
[12] *See* 510(k) Guidance at 6.
[13] *Id.* at 7.
[14] Additionally, clinicians are permitted to exercise their professional judgment in the prescription and administration of any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship, consistent with the principle known as the practice-of-medicine exemption. *See* 21 U.S.C. § 396.

robotic NSM treatment outside of the context of the IDE Study raises liability under the FDCA, the FCA, and medical malpractice laws due to its "investigational" status. These allegations are facially inaccurate. Following FDA 510(k) clearance for use of the da Vinci System in NSM, enrollment in the IDE Study concluded; indeed, the study record on www.clinicaltrials.gov makes clear that the IDE study is no longer recruiting—contrary to your assertions—and that any ongoing aspects of the study relate to long-term, secondary outcome measures.[15]

Throughout your communications, you allege that Mayo is compromising patient safety, misleading patients, and eroding trust in medicine.[16] Such allegations are both inflammatory and patently false as described above. Furthermore, they mislead cancer patients and risk undermining their confidence in the healthcare system and FDA framework at a time when informed decision-making is paramount. Mayo is relying on FDA's expert judgment in having issued a 510(k) for use of the da Vinci System for robotic NSM, as well as Mayo's own clinical experience with the device, including during the IDE study; providing patients with access to a potentially life-saving treatment that has been legally authorized for commercialization by the authoritative regulatory agency is not only entirely legal, but is also wholly in line with Mayo's commitment to providing high-quality, world-class care that serves the needs and best interests of their patients.

Now that we have corrected the factual inaccuracies underpinning your allegations, further dissemination of these allegations would be reckless and would represent a willful disregard of patient safety, in addition to the rights of Mayo Clinic. To remedy the spurious allegations put forth in your communications and to avoid the need for Mayo to undertake legal action against you, we demand that you withdraw the publications posted on Medium and immediately cease further dissemination of these false allegations in other communications media including, but not limited to, social media. We further demand that you cease all unsolicited communication—including via email, social media, or other media—with Mayo personnel regarding this matter. Mayo is monitoring the situation very closely and reserves all rights and remedies to protect the institution, employees, and their patients, including by gathering facts to support claims related to, *inter alia*, defamation, tortious interference with business relationships, and harassment.

Sincerely,

Kellie Combs

Kellie B. Combs
Gregory Levine

[15] Intuitive Surgical, Robotic vs. Open NSM for Early Stage Breast Cancer (SP NSM), NCT05720039, *available at* https://clinicaltrials.gov/study/NCT05720039?id=NCT05720039&rank=1 (last accessed Feb. 25, 2026).

[16] *See, e.g.,* Robotic NSM False Advertising Article ("When one of the nation's most reputable medical centers engages in false advertising that promotes malpractice and compromises patient safety, it not only misleads patients — it erodes trust in medicine itself").