VIA ELECTRONIC FILING

March 24, 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 Require Postmarket Surveillance, Mandate IDE and PMA Applications, Investigate Potential Misbranding, and Order a Labeling Change to Restrict enVast (K253407) to Guideline-Directed Selective/Bailout Use Only in STEMI with Persistent Large Thrombus Burden

The undersigned submits this petition under 21 C.F.R. §§ 10.20, 10.25, 10.30, and the Administrative Procedure Act. The undersigned requests that the Commissioner of Food and Drugs and the Secretary of Health and Human Services (collectively "the FDA") immediately take the following actions with respect to the NeVa PV Thrombectomy device, K253407, cleared on November 24, 2025, a/k/a enVast Coronary Thrombectomy System ("enVast"), manufactured by Vesalio Inc. ("Vesalio"):

A. Action Requested

The undersigned requests that the FDA:

1. require the manufacturer of enVast to apply for and receive an Investigational Device Exemption ("IDE") to support an eventual Premarket Approval ("PMA") for its clinical use in human patients;

2. require the manufacturer of enVast to conduct postmarket surveillance of enVast;

3. investigate whether the manufacturer's labeling of and promotional materials for enVast render it misbranded and order the manufacturer to correct the labeling and cease all false or misleading promotional claims;

4. mandate a labeling change to narrow the Indications for Use to selective or bailout use only in cases of persistent Large Thrombus Burden ("LTB") during primary percutaneous coronary intervention ("PCI") where initial standard interventions have failed or thrombus remains, and to include an explicit Class 3: No Benefit warning consistent with the 2025 American College of Cardiology ("ACC") and American Heart Association ("AHA") guideline.

These actions are necessary until long-term safety and non-inferiority to conventional guideline-directed selective/bailout thrombectomy have been established through complete clinical data (e.g., infarct size reduction, no-reflow incidence, major adverse cardiac events, and mortality)—especially given that even the existing standard of care carries a Class 3 recommendation in the 2025 ACC/AHA (i.e., No Benefit).

B. FDA Legal Authority to Act

1. *Authority to Order Postmarket Surveillance*

The FDA has authority to order postmarket surveillance. For Class II or III devices, the FDA can require postmarket surveillance when "the failure of [the device] would be reasonably likely to have serious adverse health consequences . . . ."[1] The FDA can order this surveillance "at the time of approval or clearance of a device or at any time thereafter."[2]

2. *Authority to Require IDE and PMA*

The FDA requires a sponsor to apply for IDEs to use significant risk devices in an investigation—or the FDA can require one.[3] A "significant risk device" is defined as an investigational device that:

> (1) Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;
>
> (2) Is purported or represented to be for a use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject;
>
> (3) Is 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
>
> (4) Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.[4]

An IDE may be required by the FDA for Class II or Class III devices. The key question is whether the device is significant risk, not whether it is Class II or III.

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[1] 21 U.S.C. §§ 360l(a)(1)(A)(i), (iii)(I)).
[2] 21 U.S.C. §§ 360l(a)(1)(A).
[3] 21 C.F.R. § 812.20(a)(1).
[4] 21 C.F.R. § 812.3(m).

If a device is Class III, however, a manufacturer cannot market it unless and until it applies for and receives a PMA from the FDA. In almost all cases, the FDA requires PMA to be supported by clinical data to demonstrate safety and effectiveness.[5]

3. *Authority to Mandate Labeling Changes and Address Misbranding*

A prescription device is misbranded if its labeling is false or misleading in any particular[6] or it does not bear "adequate information for use, including . . . any relevant hazards, contraindications, side effects, and precautions . . . ."[7] The FDA has authority to enforce misbranding provisions and may order corrective labeling.

C. Statement of Grounds

The FDA should take the requested actions because enVast is a new, nonstandard device with unknown risks and the potential to cause widespread harm. This Section first explains (1) the background for evaluating the enVast device. It then explains why the FDA should (2) require an IDE and (3) postmarket surveillance, (4) investigate for possible regulatory violations, and (5) mandate a label change for enVast.

1. *Background and Lack of Safety and Effectiveness Data*

The FDA cleared Vesalio's 510(k) application for enVast (K253407) without any clinical data supporting the device's safety and effectiveness in the coronary circulation.[8] In fact, data are still being gathered by the manufacturer in the ongoing NATURE trial (NCT04969471), comparing enVast as an adjunct to conventional PCI versus standard of care in ST-Elevation Myocardial Infarction (STEMI) patients with LTB. The trial's primary endpoint is infarct size (area under the curve for CK-MB activity), with secondary endpoints including MRI-assessed infarct size, salvage index, microvascular obstruction, ST-segment resolution, TIMI flow/myocardial blush grade, LV function changes, and MACE. The study is designed to detect a 30% reduction in CK-MB AUC with 90% power.

As of March 2026, the NATURE trial remains active and recruiting (or in follow-up), with no primary results published or posted on ClinicalTrials.gov. The trial's estimated completion date is September 30, 2026, meaning definitive comparative data on safety and effectiveness (including non-inferiority to standard of care) are incomplete and unavailable. Vesalio itself acknowledges this gap in its Instructions for Use (IFU), stating: "The safety and effectiveness of this device for use in the treatment of STEMI have not been established. Complications

[5] 21 U.S.C. § 360c(a)(1)(C).

[6] 21 U.S.C. § 352(a)(1).

[7] 21 C.F.R. § 801.109(d); 21 U.S.C. § 352(f)).

[8] U.S. Food & Drug Admin., 510(k) Premarket Notification: NeVa PV Thrombectomy Device (K253407), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K253407 (last updated Mar. 23, 2026).

from the use of this device in this manner could lead to death, permanent impairment, and/or the need for emergency medical intervention."[9]

By sponsoring the NATURE trial as a comparative trial against standard of care and explicitly cautioning in the IFU that safety and effectiveness in STEMI are unestablished, the manufacturer recognizes that non-inferiority (or superiority) to guideline-directed care has not been demonstrated. That is a position taken by the ACC/AHA in its 2025 guideline, which explicitly downgrades routine thrombectomy adjuncts to Class 3 Guideline Recommendation: No Benefit.

In interventional cardiology, particularly for acute STEMI with LTB, long-term clinical outcomes (e.g., infarct size, no-reflow prevention, major adverse cardiac events, and mortality) are the definitive measures of safety and effectiveness. Short-term procedural metrics (e.g., TIMI flow restoration, thrombus removal success) may not reliably predict long-term outcomes—the very evidence gap highlighted by the 2025 ACC/AHA guideline's Class 3: No Benefit recommendation against routine thrombectomy.

Although enVast is a coronary thrombectomy device, it uses a novel stent-based mechanism not covered by existing regulations or guidance documents for aspiration systems. Thus, enVast combines device elements in ways that are different from typical coronary thrombectomy devices and present new safety and effectiveness concerns. Yet the FDA cleared it as substantially equivalent to typical coronary devices. The device cannot simultaneously be "first-in-class" and substantially equivalent to a predicate device. Indeed, enVast does not have the same technological characteristics as aspiration predicates, and the broad labeling raises new questions of safety and effectiveness. There are no publicly available data that reliably demonstrate non-inferiority of enVast over existing standards of care. Further, enVast's 510(k) summary presents no clinical data in support of the clearance of enVast.

2. *The FDA Should Require Postmarket Surveillance and an IDE*

To establish the safety and effectiveness of enVast, the FDA should require Vesalio to apply for an IDE before using the device in patients.[10] The FDA should require an IDE because enVast is a "significant risk device." It is used "in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject."[11]

Requiring an IDE would have at least three benefits. First, it would protect patients. This is a high-risk patient population. Patients on whom the device is being used have acute life-threatening myocardial infarction. Many will have significant co-morbidities, including cardiogenic shock, diabetes, and multivessel disease. Not only can improper thrombus

[9] Vesalio, enVast Instructions for Use, https://www.vesalio.com/envast-ifu/ (last visited Mar. 24, 2026). *See also* U.S. Food & Drug Admin., 510(k) Premarket Notification: NeVa PV Thrombectomy Device (K253407), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K253407 (last updated Mar. 23, 2026) ("The safety and effectiveness of this device for use in the treatment of STEMI have not been established.").

[10] 21 C.F.R. § 812.20(a)(1).

[11] 21 C.F.R. § 812.3(m).

management cause harm such as larger infarct size and no-reflow, but when it occurs with embolization or vessel injury, it can lead to death of affected patients. An IDE also protects patients by requiring the manufacturer to comply with regulations governing the protection of human subjects. This guarantees that research is conducted with safeguards appropriate for emergency research. Outside the context of a properly designed and approved clinical trial, it is unclear how clinicians could plausibly fulfill the requirements of informed consent in this emergency clinical context as the device remains investigational and is not a standard of care.

Second, it would protect taxpayers. An FDA-approved IDE allows the sponsor to apply to the Centers for Medicare and Medicaid Services ("CMS") for coverage and categorization. This allows CMS to evaluate whether it should reimburse for the use of the device when used in an FDA-regulated IDE clinical trial. CMS will only pay for investigational devices that are used in an IDE trial—and not outside of it—incentivizing the firm to gather data but also compensating them for doing so.[12] Carefully calibrating reimbursement to data collection will ensure that taxpayers only pay for the device to generate enough data to decide whether to pay for it generally.

Third, it would ensure the manufacturer generates reliable safety and effectiveness data. By restricting use and payment to use in the IDE, the manufacturer would be incentivized to gather safety and effectiveness data. Moreover, the IDE regulations prohibit promoting the device, or representing it is safe and effective, for the investigated use,[13] ensuring that patients and physicians are not misled into thinking it is safe and effective until all the data are gathered.

3. *Postmarket Surveillance*

Even if the FDA does not require an IDE, it should require postmarket surveillance of enVast because any patient who experiences device failure "would be reasonably likely to have serious adverse health consequences,"[14] including but not limited to death or stroke. Given the seriousness of the potential adverse health consequences and the critical role enVast plays in thrombus management, the FDA is clearly within its authority to require postmarket surveillance of enVast. At a minimum, this should include clinical cohort studies, registries, and controls on when and where the device can be used.

4. *Potential Misbranding by the Manufacturer*

The FDA should investigate Vesalio for misbranding. The manufacturer claims that enVast is a "proven, innovative approach to clot capture and removal, redefining coronary thrombectomy for patients with large thrombus burden (LTB)"[15] and that "[c]linical experience

[12] 42 C.F.R. § 405.211.

[13] 21 C.F.R. § 812.7(a), (d).

[14] 21 U.S.C. §§ 360l(a)(1)(A)(i), (iii)(I)).

[15] Vesalio, Vesalio Receives FDA 510(k) Clearance of enVast, the First Stent-Based Coronary Thrombectomy Technology (Dec. 11, 2025), https://www.vesalio.com/vesalio-receives-fda-510k-clearance-of-envast-the-first-stent-based-coronary-thrombectomy-technology/.

internationally has consistently demonstrated its safety and effectiveness in managing complex LTB situations."

The FDA clearance of enVast redefines coronary thrombectomy treatment and further expands Vesalio's commercial platform.

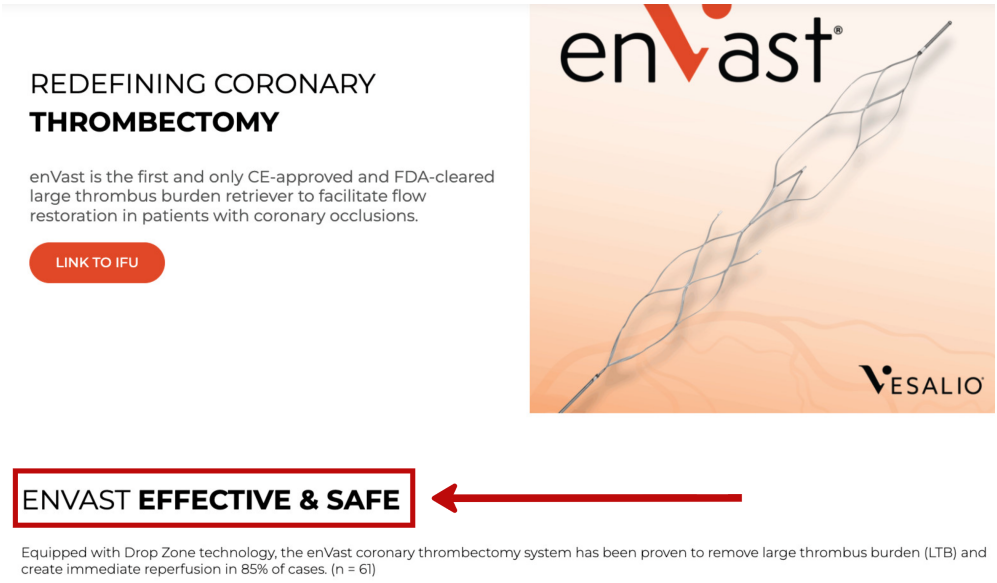
Plano, Texas – December 11, 2025

Vesalio, a leader in thrombectomy solutions, today announced FDA 510(k) clearance and the upcoming U.S. commercial launch of enVast™, the first and only clot retriever specifically cleared for mechanical thrombectomy in the cardiac circulation. enVast introduces a proven, innovative approach to clot capture and removal, redefining coronary thrombectomy for patients with large thrombus burden (LTB).

It also claims that enVast is "a simple, safe an effective procedure to overcome large thrombus burden."[16]

[16] Vesalio, Inc., enVast Brochure (2025), https://www.vesalio.com/wp-content/uploads/2025/09/VES-New-enVast-Brochure_A4-folded_FINAL.pdf (last accessed Mar. 24, 2025).

It also states it is "effective & safe."[17]



These statements contradict the label itself, which warns that "[t]he safety and effectiveness of this device for use in the treatment of ST-Elevation Myocardial Infarction (STEMI) have not been established."[18]

The 510(k) summary describing the enVast clearance contradicts the manufacturer's promotional statements that suggest the device is safe and effective for broad coronary thrombus removal in STEMI/primary PCI. In fact, long-term safety and non-inferiority data do not exist. Indeed, the manufacturer's 510(k) application included no clinical data at all. If healthcare providers adopt this device, patients may unsuspectingly be exposed to poorly understood risks of vessel injury, no-reflow, embolization, or death.

5. *Labeling*

One way to solve part of this problem is for FDA to mandate a change to enVast's label. Currently, the Indications for Use state that the device is indicated for the "non-surgical removal of thrombus burden from coronary blood vessels" (including in STEMI/primary PCI contexts), while the very same IFU explicitly warns that there is no evidence supporting that use. Because the manufacturer's own IFU precaution directly negates that assurance for the primary intended use population, the FDA should mandate a label change that is not inherently contradictory.

[17] Vesalio, Inc., Discover enVast, https://www.vesalio.com/technology/discover-envast/ (last visited Mar. 24, 2026).

[18] U.S. Food & Drug Admin., 510(k) Premarket Notification: NeVa PV Thrombectomy Device (K253407), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K253407 (last updated Mar. 23, 2026).

D. Summary of Actions Requested

For all the reasons stated above, the undersigned respectfully requests that the FDA take the following actions:

1. require the manufacturer of enVast to apply for and receive an IDE to support an eventual PMA for its clinical use in human patients;

2. require the manufacturer of enVast to conduct postmarket surveillance of enVast;

3. investigate whether the manufacturer's labeling of and promotional materials for enVast render it misbranded and order the manufacturer to correct the labeling and cease all false or misleading promotional claims;

4. mandate a labeling change to narrow the Indications for Use to selective or bailout use only in cases of persistent LTB during primary PCI where initial standard interventions have failed or thrombus remains, and to include an explicit Class 3: No Benefit warning consistent with the 2025 ACC/AHA guideline.

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.

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