June 13, 2025

Contego Medical, Inc.
Nitin Mehta
Director, Regulatory Affairs
3801 Lake Boone Trail
Suite 100
Raleigh, North Carolina 27607

Re: K251485
Trade/Device Name: Excipio LV Prime Thrombectomy Device
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEW
Dated: May 13, 2025
Received: May 14, 2025

Dear Nitin Mehta:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

GREGORY W. O'CONNELL -S

Digitally signed by GREGORY W. O'CONNELL -S
Date: 2025.06.13 08:11:54 -04'00'

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251485

Device Name
Excipio LV Prime Thrombectomy Device

Indications for Use *(Describe)*
The Excipio LV Prime Thrombectomy Device is indicated for the nonsurgical removal of emboli and thrombi from peripheral blood vessels.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY

510(k) Summary [as required per 21 CFR 807.92]

510(k) K251485

Date Prepared	June 12, 2025
Applicant:	Contego Medical, Inc. 3801 Lake Boone Trail, Suite 100 Raleigh, NC 27607
FDA RegistrationNumber	3011471056
Contact Person:	Mr. Nitin Mehta Contego Medical, Inc. 3801 Lake Boone Trail, Suite 100 Raleigh, NC 27607 Phone: + 1 805 813 7897 Email: nmehta@contegomedical.com
Proprietary Name:	Excipio LV Prime Thrombectomy Device
Common Name:	Embolectomy Aspiration Device
Device Classification:	Class II per 21 CFR §870.5150
Classification Name:	Catheter, Embolectomy
Product Code:	QEW
Predicate Device:	Excipio LV Thrombectomy Device (K223897)
Reference Devices:	Excipio SV Thrombectomy Device (K221204)

Intended Use/Indications for Use:
The Excipio LV Prime Thrombectomy Device is indicated for the non-surgical removal of emboli and thrombi from peripheral blood vessels.

Device Description:
The Excipio LV Prime Thrombectomy Device consists of a Thrombectomy Catheter to mechanically displace thrombus when used with an aspiration catheter. The device will be sold as a sterile, single use device.

Thrombectomy Catheter:
The Thrombectomy Catheter is a mechanical thrombus displacement device witha nitinol braided component (basket) at the distal end that can be opened and closed via an activation wire that attaches to the distal end of the braid and attaches to a proximal handle. The operator can open the braided component to a diameter that best matches the target vessel (6-16 mm in diameter). The thickness of the basket wires enhances the radiopacity to facilitate visualization under fluoroscopy without the need for additional

radiopaque markers.

Comparison with Predicate Devices:
A comparison of the Excipio LV Prime Thrombectomy Device (subject device) with the predicate devices shows that the technological characteristics of the subject device are the same, or similar, including the indication for use/intended use, principle of operation, design, sterilization method, and packaging.

There is no change of intended use or fundamental technology between the subject device and predicates. In addition, the subject device treats vessels within the range of the predicate devices. The Excipio LV Prime device performs thrombectomy using the same method as the predicate and reference devices.

A tabular comparison of the technological characteristics between the subject and predicate devices is provided below.

Device Name	**Excipio LV (Prime) Thrombectomy Device**	**Excipio LV Thrombectomy Device**	**Excipio SV Thrombectomy Device**
Device	**Subject Device**	**Predicate Device**	**Reference Device**
Manufacturer	**Contego Medical**	**Contego Medical**	**Contego Medical**
510(k) Number	TBD	K223897	K221204
Class/Product Code	II/QEW	II/QEW	II/QEW
Device Classification Description	Peripheral mechanical thrombectomy with aspiration	Peripheral mechanical thrombectomy with aspiration	Peripheral mechanical thrombectomy with aspiration
Indications for Use/Intended Use	Non-surgical removal of emboli and thrombi from peripheral blood vessels	Non-surgical removal of emboli and thrombi from peripheral blood vessels	Non-surgical removal of soft emboli and thrombi from peripheral blood vessels
Principle of operation - Thrombectomy mechanism	NiTi Basket	NiTi Basket	NiTi Basket
Vessel diameters to be treated	6 – 16 mm	10 – 25 mm	4 – 8 mm
Handle – Mechanism of action	Ergonomic handle	Ergonomic handle	Ergonomic handle
Basket Material	Nitinol	Nitinol	Nitinol
Basket diameter (fully expanded)	16 mm	25 mm	8 mm
Basket Braid working length	60 mm ± 5mm	82 mm minimum	34 ± 2mm
Basket Length (closed)	7 cm	10 cm	4.4 cm
Basket (max crossing profile)	0.120” (3.05mm)	0.160” (4.06mm)	0.066” (1.68mm)
Materials of Construction	Nitinol, Polyimide, Pebax, PET, SS, Loctite, Nylon, ABS, Dymax (high level)	Nitinol, Polyimide, Pebax, PET, SS, Loctite, Nylon, ABS, Dymax (high level)	Nitinol, Polyimide, Pebax, PET, SS, Loctite, Nylon, ABS, Dymax (high level)
Thrombectomy device working length	150 cm	125 cm	165 cm
Guidewire compatibility	0.035”	0.035”	0.014”
Radiopaque markers	No radiopaque markers. Basket is radiopaque itself.	No radiopaque markers. Basket is radiopaque itself.	Proximal and distal to basket and on basket circumference
Recommended Aspiration Catheter diameter	9.1 Fr inside diameter (minimum)	12.6 Fr inside diameter minimum	6.3 Fr inside diameter minimum
Aspiration Source	Vacuum (-28 in Hg)	Vacuum (-28 in Hg)	Vacuum (-28 in Hg)
Shelf Life	2 years	2 years	2 years
Sterilization	EO, Single Use device	EO, Single Use device	EO, Single Use device

Non-Clinical Testing/Performance Data:

In accordance with Contego's Risk Analysis process, non-clinical laboratory testing was performed on the Excipio LV Prime Thrombectomy Device to support the substantial equivalence of Excipio LV Prime device.

The following testing/assessments were performed:

- Visual Inspection
- Dimensional Inspection
- Kink Resistance
- Torsional Strength
- Tensile Testing
- Simulated Use
- Radial Force
- Corrosion Testing
- Compatibility Testing
- Clot removal testing

The in vitro bench tests demonstrated that the Excipio LV Prime Thrombectomy Device met all acceptance criteria, functioned as intended and has a performance profile that is similar to the predicate devices.

Biocompatibility

Biocompatibility evaluation of the Excipio LV Prime Thrombectomy Device was performed. The following aspects of biocompatibility tests were leveraged from the predicate device:

- Cytotoxicity
- Sensitization
- Intracutaneous Irritation
- Acute System Toxicity
- Material Mediated Pyrogenicity
- Hemolysis
- Complement Activation
- Thrombogenicity

The results from the evaluation performed showed the Excipio LV Prime Thrombectomy Device to be biocompatible and meets requirements per ISO 10993-1.

Sterilization and Packaging

Due to the limited nature of the device change, packaging testing was leveraged, and sterilization was assessed through sterilization adoption.

Conclusion:

The Excipio LV Prime Thrombectomy Device has the same intended use and the same or similar technological characteristics such as design, sterilization method, and operating principles as Contego's own legally marketed predicate and reference devices. None of the differences between the subject device and predicates raise any new questions of safety or effectiveness.

The conclusions drawn from the nonclinical tests demonstrate that the Excipio LV Prime Thrombectomy Device is substantially equivalent to the predicate and reference devices.