February 17, 2023

Contego Medical Inc.
Jim Clossick
Vice President of Regulatory Affairs
3801 Lake Boone Trail, Suite 100
Raleigh, North Carolina 27607

Re: K223897
Trade/Device Name: Excipio LV Thrombectomy Device
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEW
Dated: December 27, 2022
Received: December 28, 2022

Dear Jim Clossick:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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: 2023.02.17 11:39:22 -05'00'

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223897

Device Name
Excipio LV Thrombectomy Device

Indications for Use *(Describe)*

The Excipio LV Thrombectomy Device indicated for the non-surgical 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.

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

510(k) K223897

Date Prepared	December 27, 2022
Applicant:	Contego Medical, Inc. 3801 Lake Boone Trail, Suite 100 Raleigh, NC 27607
FDA RegistrationNumber	3011471056
Contact Person:	Mr. Jim Clossick Contego Medical, Inc. 3801 Lake Boone Trail, Suite 100 Raleigh, NC 27607 Phone: + 1 305 607 1708 Email: jclossick@contegomedical.com
Proprietary Name:	Excipio LV 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 SV Thrombectomy Device (K221204)
Reference Devices:	Inari Medical FlowTriever (K213402)
	Capere Thrombectomy System (K203476)

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

Device Description:
The Excipio LV 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 with a 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 (10-25mm in diameter). The thickness of the basket wires enhance the radiopacity to facilitate visualization under fluoroscopy without the need for additional radiopaque markers.

Comparison with Predicate Devices:

A comparison of the Excipio LV Thrombectomy Device with the predicate and reference devices show that the technological characteristics of the subject device such as the indication for use, principle of operation, design, and sterilization method, are similar to the currently marketed predicate device and reference device. The intended use of the subject device falls within the indication for use/intended use of the predicate device and reference devices. In addition, the subject device treats vessels within the range of reference devices. The expanded diameter, thrombectomy mechanism and its size, and aspiration catheters used are similar for the subject device in comparison to predicate and reference devices.

Device Name	**Excipio LV Thrombectomy Device**	**Excipio SV Thrombectomy Device**	**Inari Medical FlowTriever**	**CAPERE Thrombectomy System**
Device	**Subject Device**	**Predicate Device**	**Reference Device**	**Reference Device**
Manufacturer	Contego Medical	Contego Medical	Inari Medical	Vascular Medcure, Inc
510(k) Number	TBD	K221204	K213402	K203476
Class/Product Code	II/QEW	II/QEW	II/QEW, KRA	II/QEW, KRA
Device Classification Description	Peripheral mechanical thrombectomy with aspiration	Peripheral mechanical thrombectomy with aspiration	Peripheral Mechanical Thrombectomy with aspiration	Peripheral Mechanical Thrombectomy
Indications for Use/Intended Use	Non-surgical removal of emboli and thrombi from peripheral blood vessels	Non-surgical removal of soft emboli and thrombi from peripheral blood vessels	• Non-surgical removal of emboli and thrombi from blood vessels • Injection, infusion, and/or aspiration of contrast media and other fluids into or from a blood vessel The FlowTriever Retrieval/Aspiration system is intended for use in the peripheral vasculature and for the treatment of pulmonary embolism Triever Catheters are intended for use in treating clot in transit in the right atrium but no in conjunction with FlowTriever Catheters	• Non-surgical removal of soft emboli and thrombi from blood vessels. • Injection, infusion and/or aspiration of contrast media and other fluids into blood vessel. The CAPERE Thrombectomy System is intended only for use in the peripheral vasculature and is not intended for use in the pulmonary arteries
Principle of operation	Compressed NiTi Basket	Compressed NiTi Basket	Self-expanding	Expanding

Device Name	Excipio LV Thrombectomy Device	Excipio SV Thrombectomy Device	Inari Medical FlowTriever	CAPERE Thrombectomy System
Device	**Subject Device**	**Predicate Device**	**Reference Device**	**Reference Device**
- Thrombectomy mechanism			wireform disks	NiTi Basket
Basket Material	Nitinol	Nitinol	Nitinol	Nitinol
Expanded diameter	25 mm	8 mm max	6-25mm	18mm
Thrombectomy mechanism length	100 mm	40 mm	75mm	114 mm
Vessel diameters to be treated	10 – 25 mm	4 – 8 mm	6-25 mm	>10mm
Guidewire compatibility	0.035”	0.014”	0.035”	0.035”
Radiopaque markers	Proximal and distal to basket	Proximal and distal to basket and on basket circumference	Proximal and distal to wireform disks	Radiopaque Coiled and metallic construction
Aspiration Catheter diameter	14F minimum	7F or 8F	16, 20, and 24Fr	Catheter is integrated with product
Sterilization	EO	EO	EO	EO
Catheter Usable length	125 cm	165 cm	115 cm	-

Non-Clinical Testing/Performance Data:

Non-clinical laboratory testing was performed on the Excipio LV Thrombectomy Device to determine substantial equivalence. The following testing/assessments were performed:

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

The in vitro bench tests demonstrated that the Excipio LV Thrombectomy Device met all acceptance criteria and performed similarly to the predicate device. Performance data demonstrate that the device functions as intended and has a performance profile that is similar to the predicate devices.

Biocompatibility:
Biocompatibility evaluation of the Excipio LV Thrombectomy Device was performed. The following aspects of biocompatibility tests were addressed:

- Cytotoxicity
- Sensitization
- Intracutaneous Irritation
- Acute System Toxicity
- Material Mediated Pyrogenicity
- Hemolysis
- Complement Activation
- Thrombogenicity (performed on subject devices)

The results from the evaluation performed showed the Excipio LV Thrombectomy Device to be biocompatible. Biocompatibility testing was leveraged from the predicate device.

GLP Animal Study:

The study provides evidence that the Excipio LV Thrombectomy Device was safe to use in the peripheral veins in the acute swine model as evidenced by no perforations, transmural dissections, or gross thrombosis or emboli, and patent vessels after treatment when assessed by the physician in the blood vessel venographically and through histopathology.

Conclusion:

The Excipio LV Thrombectomy Device has the same intended use and the same or similar technological characteristics such as design, sterilization method, and operating principles as the predicate and reference devices. Performance data demonstrates that the device functions as intended. The conclusions drawn from the nonclinical test demonstrate that the Excipio LV Thrombectomy Device is substantially equivalent to the predicate and reference devices.