June 23, 2022

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

Re: K221204
Trade/Device Name: Excipio SV Thrombectomy Device
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEW
Dated: April 25, 2022
Received: April 26, 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 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)*
K221204

Device Name
Excipio SV Thrombectomy Device

Indications for Use *(Describe)*

The Excipio SV Thrombectomy Device is indicated for the non-surgical removal of soft 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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

510(K) K221204

Date Prepared	April 22, 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 SV Thrombectomy Device
Common Name:	Embolectomy Aspiration Device
Device Classification:	Class II per 21 CFR §870.5150
Classification Name:	Peripheral Mechanical Thrombectomy With Aspiration
Product Code:	QEW
Predicate Device:	ReVive PV Thrombectomy Device (K132281)
Reference Device:	Penumbra Indigo Aspiration System (K142870) Fogarty Arterial Embolectomy Catheter (K193379)

Intended Use/Indications for Use:

The Excipio SV Thrombectomy Device is indicated for the non-surgical removal of soft emboli and thrombi from peripheral blood vessels.

Device Description:

The Excipio SV 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 (4-8mm in diameter). Proximal and distal marker bands delineate the ends of the basket component, and 4 radiopaque markers delineate the circumference of the basket component to facilitate visualization under fluoroscopy.

Comparison with Predicate Devices

A comparison of the Excipio SV Thrombectomy Device and the predicate and reference devices show that the technological characteristics of the subject devices such as the design, sterilization method, and operating principles are similar to the currently marketed predicate and reference devices. The intended use of the subject device falls within the intended use of the predicate device.

Device Name	**Excipio SV Thrombectomy Device**	**ReVive PT Thrombectomy Device**	**Penumbra Indigo Aspiration System**	**Fogarty Arterial Embolectomy Catheter**
Device	**Subject Device**	**Predicate Device**	**Reference Device**	**Reference Device**
Manufacturer	Contego Medical	Codman & Shurtleff, Inc.	Penumbra Inc.	Baxter Healthcare Corp.
510(k) Number	K221204	K132281	K142870	K193379
Class/Product Code	II/ QEW	II/QEW	II/QEW	II/DXE, GCA
Device Classification Description	Peripheral mechanical thrombectomy with aspiration	Peripheral mechanical thrombectomy with aspiration	Peripheral mechanical thrombectomy with aspiration	Embolectomy Catheter
Indications for Use	Non-surgical removal of soft emboli and thrombi from peripheral blood vessels	Indicated for: • non-surgical removal of emboli and thrombi from peripheral blood vessels • non-surgical removal of thrombi from synthetic grafts	Removal of fresh, soft emboli and thrombi from vessels in the arterial system	Removal of fresh, soft emboli and thrombi from vessels in the arterial system.

Device Name	Excipio SV Thrombectomy Device	ReVive PT Thrombectomy Device	Penumbra Indigo Aspiration System	Fogarty Arterial Embolectomy Catheter
Device	**Subject Device**	**Predicate Device**	**Reference Device**	**Reference Device**
		• temporary use in peripheral vessel/graft occlusion • with aspiration and with the injection or infusion of contrast media and other fluids		
Principle of operation - Thrombectomy mechanism	Compressed NiTi Basket	Compressed NiTi Basket	Separator (for use in catheter lumen)	Inflatable Balloon
Expanded diameter	8 mm max	4.5mm	1.14 – 2.67 mm	4 – 14 mm
Thrombectomy mechanism length	40 mm	22-28mm	Unknown	Unknown
Artery diameters to be treated	4 – 8 mm	1.5 – 5mm	Unknown	4 – 14 mm
Guidewire compatibility	0.014”	0.014”	0.035”	N/A
Radiopaque markers	Proximal and distal to basket and on basket circumference	Proximal and distal to basket	Unknown	Barium added to catheter for radiopacity
Aspiration Catheter diameter	7F or 8F	N/A	3 – 8F	N/A
Sterilization	EO	E-beam	Unknown	Unknown

Non-Clinical Testing/Performance Data:

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

- Visual Inspection
- Dimensional Inspection
- Kink Resistance
- Torsional Strength
- Tensile Testing
- Simulated Use

The in vitro bench tests demonstrated that the Excipio SV Thrombectomy Devicemet all acceptance criteria and performed similarly to the predicate and referencedevices. Performance data demonstrate that the device functions as intended and has a safety and effectiveness profile that is similar to the predicate and reference devices.

Biocompatibility:

Testing was performed to assess biocompatibility of the Excipio SVThrombectomy Device. The following biocompatibility tests were performed:

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

The results from the testing performed showed the Excipio SV Thrombectomy Device to be biocompatible.

GLP Animal Study:

An acute GLP animal study (porcine) was conducted to evaluate in vivo thrombogenicity and acute performance and safety of the Excipio Device.

The study provides evidence that the Excipio Device was usable, non-thrombogenic, and did not raise any new questions of safety in the peripheral vasculature of the porcine model. Therefore, the device is substantially equivalent to the predicate device.

Conclusion:

The Excipio SV Thrombectomy Device has a similar 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 SV Thrombectomy Device is substantially equivalent to the predicate device.