May 30, 2023

Contego Medical, Inc.
James Clossic
Vice President, Regulatory Affairs
3801 Lake Boone Trail
Raleigh, North Carolina 27607

Re: K230030
Trade/Device Name: Excipio SV Aspiration Catheter and Tubing
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEW
Dated: April 24, 2023
Received: April 25, 2023

Dear James Clossic:

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,

For Eleni Whatley -S
Digitally signed by Eleni Whatley -S
Date: 2023.05.30 10:38:37 -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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230030

Device Name
Excipio® SV Aspiration Catheter and Tubing

Indications for Use *(Describe)*
The Excipio® SV Aspiration Catheter and Tubing is indicated for the non-surgical removal of fresh, 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.

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

510(k) K230030

Date Prepared	May 30, 2023
Applicant:	Contego Medical, Inc. 3801 Lake Boone Trail, Suite 100 Raleigh, NC 27607
FDA Registration Number	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 SV Aspiration Catheter and Tubing
Common Name:	Embolectomy Aspiration Device
Device Classification:	Class II per 21 CFR §870.5150
Classification Name:	Catheter, Embolectomy
Product Code:	QEW
Predicate Device:	Penumbra Indigo Aspiration System (K142870)

Intended Use/Indications for Use:

The Excipio SV Aspiration Catheter and Tubing is indicated for the non-surgical removal of fresh, soft emboli and thrombi from peripheral blood vessels.

Device Description:

The Excipio SV Aspiration Catheter and Tubing consists of an aspiration catheter which is a single, large inner lumen catheter with a hydrophilic coating (20cm outside the distal end) designed to navigate through the peripheral vasculature and provide the maximum luminal area for aspiration. The aspiration catheter will be available in 7F and 8F sizes. Sterile, single use aspiration tubing will be distributed to facilitate a vacuum connection between the aspiration catheter and the collection canister of the vacuum pump.

Comparison with Predicate Devices

A comparison of the Excipio SV Aspiration Catheter and the predicate device shows that the technological characteristics of the subject devices such as the design, sterilization method, and operating principles are similar to the currently marketed predicate device.

The intended use of the subject device falls within the intended use of the predicate device.

Device Name	Excipio SV Aspiration Catheter (Subject Device)	Penumbra Indigo Aspiration System (Predicate Device)
Manufacturer	Contego Medical	Penumbra Inc.
510(k) number	K230030	K142870
Class/Product Code	II/QEW	II/QEW
Indication for Use	Intended for the non-surgical removal of fresh, soft emboli and thrombi from peripheral blood vessels.	Intended for the removal of fresh, soft emboli and thrombi from vessels of the peripheral arterial and venous systems. Not for use in the coronaries or the neurovasculature
Contraindication	Not for use in the coronaries or the neurovasculature	See Intended Use above
Principle of operation - Thrombectomy mechanism	Vacuum aspiration	Vacuum aspiration
Guidewire compatibility	0.035” or smaller	0.035”
Radiopaque markers	Radiopaque marker band	Radiopaque marker band
Aspiration Catheter diameter	7F or 8F	3F – 8F
Aspiration Catheter Material - Catheter Body	Materials – Biocompatible, commonly used for interventional devices	Materials – Biocompatible, commonly used for interventional devices
Includes Aspiration Catheter - Introducer	Yes	Yes
Aspiration Catheter – Effective length:	7Fr: 120 cm ± 3 cm 8Fr: 90 cm ± 2 cm	85 -130cm
Coating	Hydrophilic coating	Hydrophilic coating
Aspiration Tubing Length	270 cm	285 cm
Compatible with Aspiration Pump	Yes (vacuum source)	Yes (vacuum source)
Sterilization	EO	EO

Non-Clinical Testing/Performance Data:

Non-clinical laboratory testing was performed on the Excipio SV Aspiration Catheter and Tubing to determine substantial equivalence. The following testing/assessment were performed:

Excipio SV Aspiration Catheter:

- Visual Inspection
- Dimensional Inspection
- Kink Resistance
- Torsional Strength
- Tensile Testing
- Functional Testing
    - Vacuum Collapse
    - Kink Resistance
    - Torque Testing
    - Tip Pull
    - Proximal Shaft to Luer
    - Coating Length
- Coating Integrity
- Particulate Testing

Tubing:

- Dimensional Inspection
- Tensile Testing
- Functional Testing
    - Vacuum Collapse
    - Kink Resistance
    - Visual Inspection

System-level Testing:

- Simulated Use Testing
- Visual Inspection
- Tubing Testing
- Packaging and Sterile Barrier Testing

The in vitro bench tests demonstrated that the Excipio SV Aspiration Catheter and Tubing met all acceptance criteria and performed similarly to the predicate device. Performance data demonstrate that the device functions as intended and is substantially equivalent to the predicate device.

Biocompatibility:

Testing was performed to assess biocompatibility of the Excipio SV Aspiration Catheter. The following biocompatibility tests were performed:

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

Testing was performed to assess the biocompatibility of the Tubing. The following biocompatibility tests were performed:

- Cytotoxicity
- Sensitization
- Irritation

The results from the testing performed showed the Excipio SV Aspiration Catheter and Tubing 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 SV Aspiration Catheter.

The study provides evidence that the Excipio SV Aspiration Catheter 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 Aspiration Catheter and Tubing has a similar intended use and the same or similar technological characteristics such as design, sterilization method, and operating principles as the predicate device.

Performance data demonstrates that the device functions as intended.

The conclusions drawn from the nonclinical test demonstrate that the Excipio SV Aspiration Catheter and Tubing does not raise new questions of safety and effectiveness compared to the predicate device. Therefore, the Excipio SV Aspiration Catheter and Tubing is substantially equivalent to the predicate device.