April 29, 2019

Meril Life Sciences Private Limited
% H. Semih Oktay
President
CardioMed Device Consultants, LLC
1783 Forest Drive, #254
Annapolis, Maryland 21401

Re: K190619
Trade/Device Name: Aspiron(TM) Aspiration Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEZ
Dated: March 8, 2019
Received: March 11, 2019

Dear Mr. Oktay:

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 and Part 809); 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190619

Device Name
Aspiron(TM) Aspiration Catheter

Indications for Use *(Describe)*
The Aspiron(TM) Aspiration Catheter is used for removal of fresh, soft emboli and thrombi from vessels in the coronary and peripheral vasculature system.

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.

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"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."

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510(k) SUMMARY

510(k) Summary

This 510(k) Summary is submitted in accordance with the requirements of 21 CFR Part 807.92.

5.1 Applicant:

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5.2 Contact Person:

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5.3 Date prepared: Jan 11, 2019

5.4 Device information:

Proprietary Name: Aspiron™ Aspiration Catheter

Common / Usual Name: Aspiration Thrombectomy Catheter

Classification Name: Embolectomy Catheter (21 CFR 870.5150, Product Code QEZ)

Device Class: Class II

5.5 Predicate device:

- Export Advance™ Aspiration Catheter (K152335)

5.6 Device description:

The Aspiron™ Aspiration Catheter is a dual lumen, rapid exchange catheter consisting of a distal tip, distal shaft, and proximal shaft with luer hub at the proximal end. The smaller of the two lumens is the Guide wire lumen (distal tip) and is compatible with 0.014" (0.36mm) guide wires. The larger diameter lumen is the extraction lumen and when used with the Aspiron™ accessories, allows for removal of thrombus. The extraction lumen is provided pre-loaded with a stylet that resists kinking during delivery. A hydrophilic coating is applied to the distal shaft. The Aspiron™ is compatible with 6F guide catheters and has a working length of 140cm. The Aspiron™ accessories include 30ml suction syringes, a one way stopcock, an extension tube, a flushing needle and 70µm filter caps.

5.7 Indication for use:

The Aspiron™ Aspiration Catheter is used for removal of fresh, soft emboli and thrombi from vessels in the coronary and peripheral vasculature system.

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5.8 Comparison of Technological characteristics:

The Aspiron™ Aspiration Catheter is similar to the predicate devices with respect to device design, materials and method of sterilization.

Comparative testing between the Aspiron™ Aspiration Catheter and Export Advance™ Aspiration Catheter found similar performance characteristics with respect to Catheter Extraction Rate, Tensile strength and Radiopacity.

The Aspiron™ Aspiration Catheter indication differs from the predicate Export Advance™ Aspiration Catheter in that the Aspiron™ Aspiration Catheter is limited to removal of fresh, soft emboli and thrombi from vessels. This difference does not raise new concerns because the more limited use of the Aspiron™ Aspiration Catheter is a more conservative indication.

5.9 Non clinical Performance data:

To ensure that the device design and construction are suitable for the intended use, the Aspiron™ Aspiration Catheter was subjected to the following performance testing:

- Dimensional verification
- Tensile Strength
- Flexibility and kink
- Torque strength
- Radiopacity
- Catheter Preparation, Extraction and Removal
- Catheter Extraction Rate (Aspiration Rate)
- Aspiration Catheter Leak
- Coating Integrity & Acute Particulate Evaluation
- Biocompatibility testing of Aspiron™ Aspiration Catheter and its accessories are in compliance with the ISO 10993-1. Aspiron™ was subjected to following tests.
  - In Vitro Cytotoxicity Study
  - Skin Sensitization Study
  - Intracutaneous reactivity test
  - Acute Systemic Toxicity Study
  - In vitro Hemolysis test Study

- Material Mediated Pyrogen Test
- In vitro C3a and SC5b-9 complement activation Test
- In Vivo Thromboresistance

The Accessories of Aspiron™ Aspiration Catheter were subjected to the following tests.

- In Vitro Cytotoxicity Study
- Skin Sensitization Study
- Intracutaneous reactivity test
- Acute Systemic Toxicity Study
- In vitro Hemolysis test Study
- Material Mediated Pyrogen Test

5.10 Conclusion

The Aspiron™ Aspiration catheter met all predetermined acceptance criteria as specified by applicable standards, FDA guidance documents and test protocols. No safety and efficacy issues were raised during the testing program.

The Aspiron™ Aspiration catheter is substantially equivalent to the predicate Export Advance™ Aspiration Catheter