DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 30, 2016

Meril Life Sciences Private Limited
% Semih Oktay, Ph.D.
CardioMed Device Consultants
5523 Research Park Drive, Suite 205
Baltimore, MD 21228

Re: K160961
Trade/Device Name: Mozec NC-Rx PTCA Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.5100
Regulation Name: Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter
Regulatory Class: Class II
Product Code: LOX
Dated: June 30, 2016
Received: July 1, 2016

Dear Dr. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Brian D. Pullin -S

for Bram D. Zuckerman, MD
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160961

Device Name
Mozec(TM) NC - Rx PTCA Balloon Dilatation Catheter

Indications for Use *(Describe)*
The Mozec(TM) NC - Rx PTCA Balloon Dilatation Catheter is indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion. The Mozec(TM) NC - Rx PTCA Balloon Dilatation Catheter is also indicated for post-delivery expansion of balloon expandable stents.

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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5. 510(k) SUMMARY

510(k) Summary

This 510(k) Summary is submitted in accordance with the requirements of 21 CFR Part 807, Section 92.

5.1 Applicant:

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5.2 Contact Person:

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5.3 Date prepared: Mar 15, 2016

5.4 Device information:

Proprietary Name:	Mozec™ NC – Rx PTCA Balloon Dilatation Catheter
Common / Usual Name:	Rapid Exchange PTCA Balloon Dilatation Catheter
Regulation name:	Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter
Regulation Number	21CFR 870.5100
Product Code:	LOX
Device Class:	Class II

5.5 Predicate device:

- NC TREK RX Coronary Dilatation Catheter (K103153) (Primary Predicate device)
- EMPIRA NC Rx PTCA Dilatation Catheter (K110133) (Secondary Predicate device)
- Mozec™ - Rx PTCA Balloon Dilatation Catheter (K131169) (Secondary Predicate device)

5.6 Device description:

Mozec™ NC - Rx PTCA Balloon Dilatation Catheter is a sterile, single use rapid exchange catheter consisting of a non-compliant balloon, a soft tip, a coaxial dual lumen distal shaft and a single lumen proximal shaft. Radiopaque platinum/iridium markers contained in the balloon segment facilitate fluoroscopic visualization of the proximal and distal ends of the Mozec™ NC balloon's working length. The Mozec™ NC balloons are offered in diameters ranging from 2.00mm to 4.50mm and lengths varying from 8mm to 38mm.

5.7 Indication for use:

The Mozec™ NC – Rx PTCA Balloon Dilatation Catheter is indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion. The Mozec™ NC - Rx PTCA Balloon

Dilatation Catheter is also indicated for post-delivery expansion of balloon expandable stents.

5.8 Comparison of Technological characteristics:

The Mozec™ NC – Rx PTCA Balloon Dilatation Catheter is the same or similar to the primary and secondary predicate devices with respect to intended use, device design, and method of sterilization. The Mozec™ NC has the same RBP as the secondary predicate EMPIRA NC and material composition of the subject device is the same as the secondary predicate Mozec™.

5.9 Non clinical Performance data:

To ensure that the device design and construction are suitable for the intended use, the Mozec™ NC – Rx PTCA Balloon Dilatation Catheter was subjected to the performance testing recommended in the *Guidance for Industry and FDA Staff- Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters* (September 8, 2010).

The safety and effectiveness of the Mozec™ NC – Rx PTCA Balloon Dilatation Catheter has been evaluated in the following non Clinical tests;

- Dimensional verification Test
- Balloon preparation, deployment and retraction Test
- Balloon rated burst pressure and Balloon compliance Test
- Balloon fatigue Test
- Balloon inflation and deflation time Test
- Bond strength Test
- Flexibility and kink test
- Balloon rated burst pressure (In stent) Test
- Balloon fatigue (In Stent) Test
- Radiopacity
- Torque test
- Performance testing on the Looper Clip accessory
- Biocompatibility testing in compliance with the ISO 10993-1
    - In Vitro Cytotoxicity study

- Skin Sensitization Study
- Intracutaneous reactivity test
- Acute Systemic Toxicity Study
- In vitro Hemolysis test Study
- In vitro C3a and SC5b-9 complement activation Assay
- Material Mediated Pyrogen Test
- In vivo thromboresistance

5.10 Conclusion

The Mozec™ NC – Rx PTCA Balloon Dilatation 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 Mozec™ NC – Rx PTCA Balloon Dilatation Catheter is substantially equivalent to the primary predicate, NC TREK RX Coronary Dilatation Catheter. Substantial equivalence is further supported with comparison to the secondary predicate devices.