May 17, 2018

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

Re: K181023
Trade/Device Name: Mozec - Rx PTCA Balloon Dilatation Catheter, 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: April 13, 2018
Received: April 17, 2018

Dear H. Semih 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.

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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)*
K181023

Device Name
Mozec – Rx PTCA Balloon Dilatation Catheter, Mozec NC – Rx PTCA Balloon Dilatation Catheter

Indications for Use *(Describe)*
The Mozec - 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 - Rx PTCA Balloon Dilatation Catheter (balloon models 2.25mm to 4.50mm) is also indicated for post delivery expansion of balloon expandable stents.

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.

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.

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6 510(k) SUMMARY

510(k) Summary

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

6.1 Applicant:

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6.2 Contact Person:

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6.3 Date prepared: April 05, 2018

6.4 Device information:

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

6.5 Predicate device:

1. Mozec™ – Rx PTCA Balloon Dilatation Catheter (K131169)
2. Mozec™ NC – Rx PTCA Balloon Dilatation Catheter (K160961)

6.6 Device description:

a. Mozec – Rx PTCA Balloon Dilatation Catheter

Mozec - Rx PTCA Balloon Dilatation Catheter is a sterile, single use rapid exchange catheter consisting of a semi-compliant balloon, a soft tip, a dual lumen distal shaft and a single lumen proximal shaft. Radiopaque platinum/iridium marker(s) contained in the balloon segment facilitate fluoroscopic visualization of the proximal and distal ends of the Mozec balloon's working length (2.00 mm to 4.50 mm sizes) or the centre of the balloon's working length (1.50 mm size). The Mozec balloons are offered in diameters ranging from 1.50 mm to 4.50 mm and lengths varying from 9 mm to 41 mm.

b. Mozec NC – Rx PTCA Balloon Dilatation Catheter

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 dual lumen distal shaft and a single lumen proximal shaft. Radiopaque

platinum/iridium marker(s) 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 2.00 mm to 4.50 mm and lengths varying from 8 mm to 38 mm.

6.7 Indication for use:

a. Mozec™ – Rx PTCA Balloon Dilatation Catheter

The Mozec™ - 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™ - Rx PTCA Balloon Dilatation Catheter (balloon models 2.25 mm to 4.50 mm) is also indicated for post delivery expansion of balloon expandable stents.

b. Mozec™ NC – Rx PTCA Balloon Dilatation Catheter

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.

6.8 Comparison of Technological characteristics:

The Mozec – Rx PTCA Balloon Dilatation Catheter and Mozec NC – Rx PTCA Balloon Dilatation Catheter are similar to the predicate devices with respect to intended use, device design, materials, rated burst pressure, and method of sterilization.

6.9 Non clinical Performance data:

To ensure that the modifications made to the devices are suitable for the intended use, the modified devices were 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 modified Mozec and Mozec NC has been evaluated in the following non clinical tests;

- Dimensional verification
- Balloon preparation, deployment and retraction
- Balloon rated burst pressure
- Balloon compliance
- Balloon inflation and deflation time
- Catheter bond strength(s)
- Flexibility and kink test

6.10 Conclusion

The Mozec – Rx PTCA Balloon Dilatation Catheter and 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.

Both the devices i.e. Mozec and Mozec NC are similar to the predicate devices with respect to intended use, device design, materials, rated burst pressure, and method of sterilization. Therefore, Meril Life Sciences Pvt. Ltd. believes the modified Mozec – Rx PTCA Balloon Dilatation Catheter and Mozec NC – Rx PTCA Balloon Dilatation Catheters are considered substantially equivalent to the predicate devices.