July 2, 2021

Kossel Medtech (Suzhou) Co., Ltd.
Maggie Xu
Deputy Manager of Regulatory Affairs
F2-3, BLDG 6, No. 8, Jinfeng Road
Suzhou New District, Jiangsu Province
P.R. China

Re: K211393
Trade/Device Name: Selethru™ NC 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 29, 2021
Received: May 5, 2021

Dear Maggie Xu:

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:

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: *K211393*

Device Name
Selethru™ NC PTCA Balloon Dilatation Catheter

Indications for Use *(Describe)*
The Selethru™ NC 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.

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."

5 510(K) SUMMARY OR 510(K) STATEMENT

Submitter:	Kossel Medtech (Suzhou) Co., Ltd. F2-3, BLDG 6, No. 8 Jinfeng Road Suzhou New District, JiangSu Province, P.R. China
Contact Person:	Maggie Xu F2-3, BLDG 6, No. 8 Jinfeng Road Suzhou New District, JiangSu Province, P.R. China Phone: +86 150 5147 6125 E-mail: 916176651@qq.com
Prepared Date:	April 29th, 2021
Trade Name:	Selethru™ NC PTCA Balloon Dilatation Catheter
Common Name:	Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter
Classification Name:	Catheters, transluminal coronary angioplasty, percutaneous (21 CFR 870.5100), Class II (special controls) Product Code: LOX
Predicate Device:	Primary Predicate: NC Emerge™ Monorail (MR) PTCA Dilatation Catheter (K141236; cleared August 7, 2014)
Reference Device:	Single Reference Device: Apollo Balloon Dilatation Catheter (K153742; cleared August 8, 2016)
Device Description:	The Selethru™ NC PTCA Balloon Dilatation Catheter is a rapid exchange (RX) PTCA Balloon Catheter used for the purpose of dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion. And it is a sterile, single-use, intravascular medical device with a working length of 142cm. The non-compliant balloons are available in diameters 2.0 and 5.0mm and lengths from 6-30mm, and have a rated burst pressure of 22 atm for φ2.0 mm and 20 atm for φ5.0mm. The proximal shaft is PTFE coated stainless steel tube, which allows for exceptional push ability and a smooth transition to the distal shaft, which is composed of an outer tube, an inner tube, and a balloon. A hydrophilic coating is applied to the distal section. Moreover, the proximal shaft of the catheter has two marker sections of 5mm length that aid in gauging dilatation catheter position relative to the guiding catheter tip (marker located closest to the dilatation catheter adaptor is for femoral guiding catheters and the other marker is for brachial guiding catheters). The distal shaft of the catheter has an integrated shaft system. The shaft has a combination of single lumen and dual lumen tubing. One lumen is used for inflation of the balloon with contrast medium. The other lumen, in the distal shaft, permits the use of a guide wire to facilitate advancement of the dilatation catheter to and through the stenosis to be dilated. The guidewire enters the catheter tip and advances coaxially out the distal Rx port, thereby allowing both coaxial guidance and rapid exchange of the catheter with a single standard length guidewire.

	Two radiopaque Platinum/Iridium marker bands are located within the balloon segment to aid in positioning the balloon in the stenosis, and are designed to provide an expandable segment of known diameter and length at a specific pressure. The design of this dilatation catheter does not incorporate a lumen for distal dye injections and distal pressure measurements.
Intended Use:	The Selethru™ NC 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.
Technological Characteristics:	Comparisons of the new and predicate devices show that the technological characteristics such as product performance, design, and intended use are substantially equivalent to the currently marketed predicate devices.
Performance Data:	Both *in vitro* performance tests, such as dimensional verification, balloon rated burst pressure, balloon fatigue, balloon compliance, balloon inflation and deflation time, catheter bond strength, tip pull strength, flexibility and kinking, torque strength, radiopacity, coating integrity, and particulate evaluation, and also biocompatibility tests, such as cytotoxicity, sensitization, intracutaneous reactivity, acute systemic toxicity, hemocompatibility (hemolysis, complement activation, and *in vivo* thromboresistance), pyrogenicity were conducted. The test results met all acceptance criteria and ensure that the Selethru™ NC Catheter design and construction are suitable for its intended use as recommended by the Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters (FDA; September 8, 2010).
Conclusion:	This information supports a determination of substantial equivalence between the Selethru™ NC PTCA Balloon Dilatation Catheter and the predicate devices described above.