January 7, 2022

Kossel Medtech (Suzhou) Co., Ltd.
Zane Wang
Quality Director
F2-F3, BLDG 6, No. 8, Jinfeng Road
Suzhou, Jiangsu Province 215163
China

Re: K211349
Trade/Device Name: Selebrek 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: December 2, 2021
Received: December 8, 2021

Dear Zane Wang:

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,

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)*
K211349

Device Name
Selebrek PTCA Balloon Dilatation Catheter

Indications for Use *(Describe)*
The Selebrek 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.

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510(k) Summary – K211349

This 510(k) Summary is submitted in accordance with 21 CFR 807.92(c).

Submitter:	Kossel Medtech (Suzhou) Co., Ltd. F2-F3, BLDG 6, No. 8 Jinfeng Road Suzhou New District, Jiangsu Province, China
Contact Person:	Zane Wang F3, BLDG 6, No. 8 Jinfeng Road Suzhou New District, Jiangsu Province, China Phone: +86 512 8717 4080-6003 Mail: wangzhigao@kosselmed.com
Date Prepared:	December 30, 2021
Trade Name:	Selebrek 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:	Sapphire II PRO Balloon Dilatation Catheter (K180921; cleared June 28, 2018)

Intended use/Indication for use:

The Selebrek 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.

Device Description:

The Selebrek PTCA Balloon Dilatation Catheter is a rapid exchange (RX) PTCA Balloon Dilatation 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.

The Selebrek is a sterile, single-use, intravascular medical device with a working length of 142cm. 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. The semi-compliant balloons are available in diameters of 1.5mm and lengths from 6-30mm, and have a rated burst pressure of 14 atm.

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.

One radiopaque Platinum/Iridium marker band is 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.

Comparison with predicate device:

Percutaneous Transluminal Coronary Angioplasty (PTCA) is the technological principle for both Selebrek PTCA Balloon Dilatation Catheter and the predicate device. PTCA is based on the use of Percutaneous Coronary Intervention (PCI) devices for the purpose of myocardial perfusion.

The Selebrek PTCA Balloon Dilatation Catheter and predicate device have following same technological elements:

- Operating principle – balloon dilatation of stenotic portion by pressurization of inflation medium
- Intended User – for patients evidencing coronary ischemia for the purpose of improving myocardial perfusion
- Fundamental catheter design – balloon, shaft, radiopaque marker, hub, coating
- Shaft type – Rapid exchange
- Sterilization – Ethylene oxide
- Pressure – Nominal Pressure and Rated Burst Pressure

There are following minor technological differences between Selebrek PTCA Balloon Dilatation Catheter and predicate device:

- Combination of balloon diameter and balloon length
- Distal shaft diameters
- Catheter effective length
- Crossing profile
- Marker bands
- Miniwrap folds

Any differences that exist between the Selebrek PTCA Balloon Dilatation Catheter and the predicate device did not raise any new questions of safety or effectiveness.

Comparison items	Subject Device Selebrek PTCA Balloon Catheter	Predicate Device Orbus Neich Medical, Sapphire II PRO Balloon Dilatation Catheter K180921	Comments
Intended Use/Indications for use	The Selebrek 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 Sapphire® II PRO Balloon Dilatation Catheter (Ø1.0-1.25mm configurations) is indicated for: ● Balloon pre-dilatation of a stenotic portion of a coronary artery or bypass graft stenosis (≥70% stenosis) for the purpose of improving myocardial perfusion. The Sapphire® II PRO Balloon Dilatation Catheter (Ø1.5-4.0mm configurations) is indicated for: ● ***Balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis in patients evidencing coronary ischemia for the purpose of improving myocardial perfusion.*** ● Balloon dilatation of a coronary artery occlusion for the treatment of acute myocardial infarction. The Sapphire® II PRO Balloon Dilatation Catheter is also indicated for: ● percutaneous transluminal angioplasty in the peripheral vasculature, including renal, femoral, popliteal, infra-popliteal, tibial, and peroneal arteries.	● The intended use of predicate device is larger than that of the subject device, which not only for coronary use but also support the peripheral use; ● The intended use of subject device is identical to that of the predicate device balloon size 1.5~4.0mm, while the description of predicate device is more detailed and specific. ● The Subject Device Selebrek PTCA Balloon Catheter is intended use in patients evidencing coronary ischemia for improving myocardial perfusion. The differences in description are not critical to the intended therapeutic, or surgical use of the device, so the differences do not raise any new questions of safety or effectiveness

Comparison items		Subject Device Selebrek PTCA Balloon Catheter	Predicate Device Orbus Neich Medical, Sapphire II PRO Balloon Dilatation Catheter K180921	Comments
Classification name		Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter 21 CFR 870.5100 (class II, special control)	Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter 21 CFR 870.5100 (class II, special control)	Identical
Product code		LOX	LOX	Identical
Chemical composition	Balloon material	Pebax	Pebax	Identical
	Coating	PTFE / Hydrophilic	Hydrophilic (distal tip to guidewire exit marker); Hydrophobic (guidewire lumen)	Equivalent
Physical characteristics /Device design	Balloon Diameters (mm)	1.5	1.0 – 4.0	Equivalent
	Balloon lengths (mm)	6-30	5-30	Equivalent
	Balloon compliance	Semi-Compliant	Semi-Compliant	Identical
	Catheter Type	Rx	Rx	Identical
	Marker bands	1 marker	1.0-1.5mm: 1 marker 1.5-4.0mm: 2 markers	Equivalent

Comparison items		Subject Device Selebrek PTCA Balloon Catheter	Predicate Device Orbus Neich Medical, Sapphire II PRO Balloon Dilatation Catheter K180921	Comments
	Guide wire size (inch)	0.014"	0.014"	Identical
	Proximal shaft diameter	2.0 F	2.0 F	Identical
	Distal shaft diameter	2.36 F	1.0-1.5mm: 2.36F 1.75-4.0mm: 2.36F – 2.7F	Equivalent
	Crossing Profile (inch)	0.026"~0.043"	3.0mm: 0.031"	Equivalent
	Miniwrap folds	3 folds	1.0mm: 2 folds; 1.25-4.0mm: 3 folds	Equivalent
	Catheter length (cm)	142	140	Equivalent
	Rated burst Pressure (atm)	14	14	Identical
	Nominal pressure (atm)	6	6	Identical
Sterilization Method		EO	EO	Identical

Non-clinical testing/Performance data:

Non-clinical bench testing was performed on the subject device to determine substantial equivalence. The testing performed is as follows:

- 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
- Particulate evaluation
- Shelf life testing

The results met all acceptance criteria and ensure that the Balloon Dilatation 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).

Biocompatibility:

To demonstrate the biological safety of the body-contacting materials and substantial equivalence of the Selebrek PTCA Balloon Dilatation Catheter to the compared device Selethru PTCA Balloon Dilatation Catheter which had been cleared by FDA (K182699), the following biocompatibility testing, which was performed on the compared device (Selethru PTCA Balloon Dilatation Catheter) in accordance with "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"; Guidance for Industry and Food and Drug Administration Staff" were leveraged:

Cytotoxicity, sensitization, intracutaneous reactivity, acute systemic toxicity, hemocompatibility (hemolysis, complement activation, and in vivo thromboresistance), pyrogenicity were conducted.

The results of the testing show that the subject device included in this submission met all acceptance criteria and the subject device is biocompatible.

Conclusion:

The Selebrek PTCA Balloon Dilatation Catheter included in this notification is equivalent to the previously cleared predicate device, the Sapphire® II PRO PTCA Balloon Dilatation Catheter (K180921) in terms of intended use and technological characteristics. Any differences that exist between the Selebrek PTCA Balloon Dilatation Catheter and the predicate device did not raise any new questions of safety or effectiveness.