December 14, 2022

Kossel Medtech (Suzhou) Co., Ltd.
Ron Lv
Regulatory Affair Engineer
BLDG 6, No. 8, Jinfeng Road
Suzhou, Jiangsu Province 215163
China

Re: K221245
Trade/Device Name: PTA Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT
Dated: November 1, 2022
Received: November 7, 2022

Dear Ron Lv:

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 W. O'connell -S

Digitally signed by Gregory W. O'connell -S
Date: 2022.12.14 13:02:23 -05'00'

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)*
K221245

Device Name
PTA Balloon Dilatation Catheter

Indications for Use *(Describe)*
The PTA balloon dilatation catheter is indicated for the percutaneous transluminal angioplasty (PTA) of the peripheral vascular system, including the iliac, femoral, ilio-femoral, popliteal, infra-popliteal and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

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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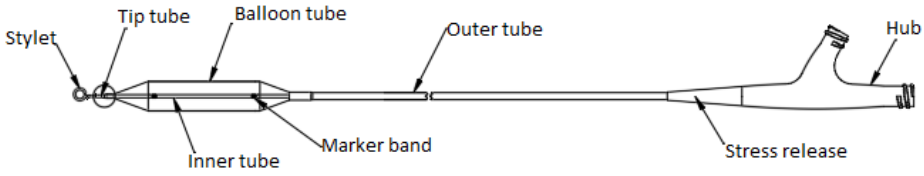
510(k) SUMMARY

Submitter:	Kossel Medtech (Suzhou) Co., Ltd. BLDG 6, No. 8 Jinfeng Road Suzhou New District, Jiangsu Province, China
Contact Person:	Ron Lv F3, BLDG 6, No. 8 Jinfeng Road Suzhou New District, Jiangsu Province, China Phone: +86 150 5142 9102 Mail: lvxin@kosselmed.com
Date Prepared:	November 22, 2022
Trade Name:	PTA Balloon Dilatation Catheter
Common Name:	Percutaneous Transluminal Angioplasty (PTA) Catheter
Classification Name:	Catheter, Angioplasty, Peripheral, Transluminal (21 CFR 870.1250), Class II (special controls)
Product Code:	LIT
Predicate Device:	Predicate Device: SABER .018 Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter (K133843, cleared May 19, 2014)
Device Description:	The 0.0180″ PTA balloon dilatation catheter is mainly composed of tip tube, inner tube, balloon, marker bands, outer tube, stress release tube and hub. Among them the balloon is the most important part of the catheter. In order to dilate different stenosis, the balloon should be dilated to difference dimension by inflating different pressure. The soft tip at the end of the balloon is to make the balloon catheter more easily to push to the stenosis position. The inner tubing which connects to the tip tubing is for guide wire passage and the pushing road. The two marker bands which wrapping on the inner tubing are for positioning the balloon location by cooperating in vitro monitoring equipment. The distal of the outer tube is connected with the balloon by a variable-diameter stretching structure, which can make the balloon get smaller winding diameter. The proximal of the outer tube is connected with the hub as the inflation passage and the pushing shaft. The hub is for connecting the outer pressure filling equipment. The stress release tubing is for protecting the outer tube from bending. The outer surface of the catheter is coated with a hydrophilic coating that ranges 400mm in length from the tip tube to the proximal end of the balloon, including part of the outer tube.



Intended Use/ Indications for Use: The PTA balloon dilatation catheter is indicated for the percutaneous transluminal angioplasty (PTA) of the peripheral vascular system, including the iliac, femoral, ilio-femoral, popliteal, infra-popliteal and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

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.

The following table lists the material and size comparisons between the subject device and the predicate device.

Technological Characteristics	**PTA Balloon Dilatation Catheter**	**Predicate Device**	**Comparison**
		SABER® PTA Dilatation Catheter K133843	
Balloon material	Nylon12	Nylon12	Identical
Coating	Hydrophilic	Hydrophilic	Identical
Balloon Diameters (mm)	2.0~7.0	2.0~10.0	Equivalent
Balloon lengths (mm)	20~300	20~300	Identical
Balloon compliance	Semi-Compliant	Semi-Compliant	Identical
Catheter Type	OTW	OTW	Identical
Guide wire size (inch)	0.018″	0.018″	Identical
Sheath Compatibility	6F	6F	Identical
Proximal shaft diameter	4.0F(1.32mm)/4.7F(1.55mm)	3.9F/4.7F	Equivalent
Distal shaft diameter	4.0F(1.32mm)/4.7F(1.55mm)	3.9F/4.7F	Equivalent
Catheter length (cm)	90/150	90/150	Identical
Rated burst Pressure (atm)	16atm (ø2.0-2.5×20-120mm); 14atm (ø2.0-2.5×150-300mm, ø5.0-6.0×20-120mm); 12atm (ø5.0-6.0×150-300mm, ø7.0×20-120mm); 10atm (ø7.0×150-300mm)	18atm (ø2.0-2.5mm， ø3.0-4.0×20-100mm); 16atm(ø5.0-6.0×20-100mm); 14atm (ø7.0mm， ø3.0-6.0×150-300mm); 12atm (ø8.0mm); 10atm (ø9.0-10.0mm)	Equivalent

Technological Characteristics	**PTA Balloon Dilatation Catheter**	**Predicate Device**	**Comparison**
		SABER® PTA Dilatation Catheter K133843	
Nominal pressure (atm)	6	6/8	Equivalent
Sterilization Method	EO	EO	Identical

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

- Operating principle – balloon dilatation of stenotic portion by pressurization of inflation medium
- Fundamental catheter design – balloon, shaft, radiopaque marker, hub, coating
- Balloon Length
- Balloon compliance – Semi-Compliant
- Catheter type – OTW
- Guide wire size
- Sheath Compatibility
- Catheter effective length
- Sterilization – Ethylene oxide

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

- Combination of balloon diameter
- Proximal/Distal shaft diameters
- Pressure – Nominal Pressure and Rated Burst Pressure

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

Performance Data: Bench testing was performed on the subject device to determine substantial equivalence. The testing performed is as follows:

- Visual inspection
- Dimensional verification
- Hydration test
- Leakage test
- Balloon inflation and deflation time
- Balloon fatigue
- Radiopacity
- Simulated use test/guidewire and introducer sheath compatibility test
- Tip pull strength
- Catheter bond strength
- Torque strength
- Balloon rated burst pressure
- Balloon compliance
- Catheter body burst pressure
- Flexibility and kinking
- Coating integrity
- Particulate evaluation
- Infusion flow rate
- Corrosion resistance test
- Packaging performance Test (Visual inspection, Sealing strength, Sealing integrity, Sterility)
- 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 draft Peripheral Percutaneous Transluminal Angioplasty (PTA) and Specialty Catheters - Premarket Notification (510(k)) Submissions (FDA; January 13, 2020).

Biocompatibility To demonstrate the biological safety of the body-contacting materials, the following biocompatibility testing, which was performed in accordance with 'Use of International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk mangement process'; draft 'Peripheral Percutaneous Transluminal Angioplasty (PTA) and Specialty Catheters - Premarket Notification (510(k)) Submissions' were followed. Cytotoxicity, sensitization, intracutaneous reactivity, acute systemic toxicity, hemocompatibility (hemolysis, partial thromboplastin time, complement activation, and in vivo thromboresistance), material-mediated 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: This information supports a determination of substantial equivalence between the PTA Balloon Dilatation Catheter and the predicate device described above.