December 20, 2023

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

Re: K231402
Trade/Device Name: HP PTA Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT
Dated: November 13, 2023
Received: November 17, 2023

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Ariel G. Ash-shakoor -S
Digitally signed by Ariel G. Ash-shakoor -S
Date: 2023.12.20 09:49:01 -05'00'

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 *(if known)*
K231402

Device Name
HP PTA Balloon Dilatation Catheter

Indications for Use *(Describe)*
The HP PTA Balloon Dilation Catheter is indicated for Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature, including iliac, femoral, popliteal, tibial, peroneal, and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

This catheter is not for use in coronary arteries.

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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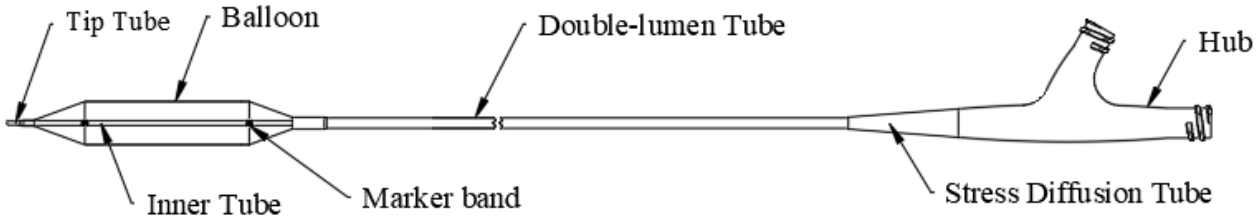
510(k) SUMMARY

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:	May 12, 2023
Trade Name:	HP 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: Mustang™ Balloon Dilatation Catheter (K103751, cleared MAR 22, 2011)
Device Description:	The 0.0350″ HP PTA balloon dilatation catheter is mainly composed of tip tube, inner tube, balloon, marker bands, double-lumen tube, stress diffusion 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 different dimensions by inflating to different pressures. The soft tip at the end of the balloon is intended to make the balloon catheter more easy to push to the stenosis position. The inner tube which connects to the tip tube is for guide wire passage and the pushing rod. The two marker bands wrapped around the inner tube are for positioning the balloon location with the use of in vitro monitoring equipment. The proximal end of the double-lumen tube is connected with the hub, which is used as the balloon filling channel and also as the push rod of the catheter. The hub is used to connect with the external pressure equipment for balloon filling. The stress diffusion tube can prevent the double-lumen tube from being folded.



Intended Use: The HP PTA Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature, including iliac, femoral, popliteal, tibial, peroneal, and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

This catheter is not for use in coronary arteries.

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	**HP PTA Balloon Dilatation Catheter**	**Predicate Device**	**Comparison**
		Mustang™ Balloon Dilatation Catheter K103751	
Balloon material	Nylon, Pebax	Nylon, Pebax	Equivalent
Balloon Diameters (mm)	3.0~12.0	3.0~12.0	Identical
Balloon lengths (mm)	20~200	20~200	Identical
Balloon compliance	Non-Compliant	Non-Compliant	Identical
Catheter Type	OTW	OTW	Identical
Guide wire size (inch)	0.035″	0.035″	Identical
Sheath Compatibility	8F	7F	Different
Double lumen tube diameter	5.3F(1.78mm)	unknown	/
Catheter length (cm)	40/75/135	40/75/135	Identical
Rated burst Pressure (atm)	24atm (ø3.0-4.0mm); 22atm (ø5.0-6.0mm); 20atm (ø7.0×20-100mm); 18atm (ø7.0×120-200mm，ø8.0-9.0mm) 14atm (ø10.0-12.0mm)	24atm (ø3.0-5.0mm，ø6.0×20-100mm); 22atm(ø6.0×120-200mm); 20atm (ø7.0×20-100mm，ø8.0×20-100mm); 18atm (ø7.0×120-200mm，ø8.0×120-200mm，ø9.0mm); 14atm (ø10.0-12.0mm)	Equivalent
Nominal pressure (atm)	8/10	8/10	Equivalent
Sterilization Method	EO	EO	Identical

The HP 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
- Balloon Diameter and Length
- Balloon compliance – Non-Compliant
- Catheter type – OTW
- Guide wire size
- Catheter effective length
- Nominal Pressure
- Sterilization – Ethylene oxide

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

- Double lumen tube diameter
- Sheath Compatibility
- Rated Burst Pressure

Any differences that exist between the HP 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
- 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 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 management process'; 'ASTM F2888-19 Standard Practice for Platelet Leukocyte Count—An ln-Vitro Measure for Hemocompatibility Assessment of Cardiovascular Materials'; '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, in vivo thromboresistance and thrombus electron microscope scanning), material-mediated pyrogenicity and platelet leukocyte count study 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 HP PTA Balloon Dilatation Catheter and the predicate devices described above.