September 7, 2018

Promepla Sam
Alexandre Bareille
Regulatory Affairs Manager
9 Avenue Albert II
MC 98000
Monaco

Re: K182144
Trade/Device Name: Bi-Flex Evo
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: II
Product Code: KNY
Dated: July 9, 2018
Received: August 8, 2018

Dear Alexandre Bareille:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Mark R. Kreitz -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological 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)*
K182144

Device Name
Bi-Flex Evo

Indications for Use *(Describe)*
The BiFlex Evo is intended to be a conduit for passage of endoscopes and other urological devices for the purpose of performing ureteroscopy procedures. The dual working lumen dilator with luer lock connections allows the user to insert guidewires and fluids

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

A. Submitter Information

Submitter's Name:	PROMEPLA SAM
Address	9 Avenue Albert II 98000 Monaco MONACO (Principality of)
Contact Person	Alexandre Bareille *Regulatory Affairs Manager*
Contact Person's email:	alb@promepla.com
Contact Person's Number	(377) 979-842-44
Contact Person's Fax	(377) 920-561-50
Submission date	July 09, 2018

B. Device Name

Trade Name of the Device:	Bi-Flex Evo
Common Name:	Accessories, Catheter, G-U
Regulation Number:	876.5130
Regulation Name:	Urological catheter and accessories
Regulation Class:	II
Product Code:	KNY
Panel:	Gastroenterology/Urology
Official Contact Person:	Alexandre Bareille

C. Predicates Devices

N°	Product name	Manufacturer	510(k) number
1	Bi-Flex Ureteral Access Sheath	PROMEPLA SAM	K140441

D. Device Description:

The Bi-Flex Evo Ureteral Access Sheath is designed to create a conduit for urological procedural instruments. The device consists of two components: a flexible, coil reinforced sheath and a semi-rigid dual lumen dilator catheter with tapered distal tip. Both components are radiopaque and have hydrophilic coating. This device is sold in two sizes,10/12 and 12/14 FR, and two lengths, 35 and 45 cm.

E. Indications for Use:

The Bi-Flex EVO Ureteral Access Sheath is intended to be a conduit for passage of endoscopes and other urological devices for the purpose of performing ureteroscopy procedures. The dual working lumen dilator with luer lock connections allows the user to insert guidewires and fluids.

F. Technological Characteristics and Performance Data:

The changes are modifying the material of the dilator from LDPE to Polyurethane to be able to allow a safer introduction thanks to the increased flexibility of its tapered tip. In addition, the Bi-Flex Evo has marks printed on the dilator, allowing an easier visualization of penetration depth and thus a safer insertion into patient.

In support of this 510(k) premarket notification, Promepla SAM has conducted bench testing to demonstrate that Bi-flex Evo Ureteral Access Sheath provide adequate mechanical strength for their intended use.
All bench testing results confirmed that the products described in this submission met the necessary specification.
In addition, the biocompatibility of the devices has been confirmed in accordance with ISO 10993, and the company has conducted sterilization validation in accordance with recognized industry standards.
A list of the tests performed to support substantial equivalence is provided below:

- Sterilization Validation;
- Biocompatibility;
- Device verification and validation;

The results of these evaluations demonstrate that the Bi-Flex Evo are safe and effective when used in accordance with their intended use and labeling.

G. Conclusion

Promepla SAM has demonstrated that the proposed Bi-Flex Evo Ureteral Access Sheaths are substantially equivalent to Promepla SAM's currently marketed Bi-Flex Ureteral Access Sheath (K140441) and that the Bi-Flex Evo are safe and effective when used in accordance with their intended use and labeling
The modifications do not affect the intended use of the device or alter the fundamental scientific technology of the device.