April 23, 2020

Promepal Sam
Mohamed Rekik
QRA Manager
9 Avenue Albert II
Monaco, 98000
MONACO

Re: K192183
Trade/Device Name: RocaTub Ureteral Catheter
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological Catheter and accessories
Regulatory Class: Class II
Product Code: EYB
Dated: March 13, 2020
Received: March 23, 2020

Dear Mohamed Rekik:

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
Purva Pandya
Acting Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192183

Device Name
RocaTub Ureteral catheter

Indications for Use *(Describe)*

The RocaTub ureteral catheter is intended for use during ureteral catheterization for drainage, opacification of the upper urinary tract (retrograde ureteropyelography) and flushing procedures for diagnostics or interventional endourology procedures (stone management, stricture management) on adults.

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.

510 (k) Summary

A. Submitter Information

Submitter's Name:	PROMEPLA SAM
Address	9 Avenue Albert II 98000 Monaco MONACO (Principality of)
Contact Person	Mohamed REKIK *QRA Manager*
Contact Person's email:	mr@promepla.com
Contact Person's Number	(377) 979-842-44
Contact Person's Fax	(377) 920-561-50
Submission date	April 17th, 2020

B. Device Name

Trade Name of the Device:	RocaTub Ureteral Catheter
Common Name:	Catheter, Ureteral, Gastro-Urology
Classification Name:	Urological catheter and accessories
Device Class:	2
Panel:	Gastroenterology/Urology
Product Code	EYB
Classification Regulation	21 CFR 876.5130
Official Contact person	Mohamed REKIK

C. Predicate Device

N°	Product name	Manufacturer	510(k) number
1	Ureteric catheters	Coloplast corp	K182122

D. Device Description:

The Rocamed RocaTub Catheters consist of a flexible tube, tapered, perforated and with position marks. It is radio-opaque and hydrophilic coated. The device includes a stylet for easing insertion into the patient if needed and a connector for syringe for flushing procedures. The device is offered in various sizes, from 4 to 7 Fr in 80cm length, and with various tip shapes.

Reference	Diameter (Fr)	Length (cm)	Designation of the product
ROTA4200ST	4	80	ROCATUB CATHETER - 2 EYES - Straight/Open distal tip - 80 cm - 4Fr

ROTA5200ST	5	80	ROCATUB CATHETER - 2 EYES - Straight/Open distal tip - 80 cm - 5Fr
ROTA6200ST	6	80	ROCATUB CATHETER - 2 EYES - Straight/Open distal tip - 80 cm - 6Fr
ROTA7200ST	7	80	ROCATUB CATHETER - 2 EYES - Straight/Open distal tip - 80 cm - 7Fr
ROTG4000ST	4	80	ROCATUB CATHETER - NO EYES - Straight/Open distal tip - 80 cm - 4Fr
ROTG5000ST	5	80	ROCATUB CATHETER - NO EYES - Straight/Open distal tip - 80 cm - 5Fr
ROTG6000ST	6	80	ROCATUB CATHETER - NO EYES - Straight/Open distal tip - 80 cm - 6Fr
ROTG7000ST	7	80	ROCATUB CATHETER - NO EYES - Straight/Open distal tip - 80 cm - 7Fr
ROTH4000ST	4	80	ROCATUB CATHETER - NO EYES - Curved/Open distal tip - 80 cm - 4Fr
ROTH5000ST	5	80	ROCATUB CATHETER - NO EYES - Curved/Open distal tip - 80 cm - 5Fr
ROTH6000ST	6	80	ROCATUB CATHETER - NO EYES - Curved/Open distal tip - 80 cm - 6Fr
ROTH7000ST	7	80	ROCATUB CATHETER - NO EYES - Curved/Open distal tip - 80 cm - 7Fr

E. Indications for Use:

The RocaTub ureteral catheter is intended for use during ureteral catheterization for drainage, opacification of the upper urinary tract (retrograde ureteropyelography) and flushing procedures for diagnostics or interventional endourology procedures (stone management, stricture management) on adults.

F. Summary of Non-Clinical Performance Testing:

In support of this 510(k) premarket notification, Promepla SAM has conducted bench testing to demonstrate that the RocaTub Ureteral Catheter provide adequate mechanical strength for their intended use.
All bench testing results confirmed that the products described in this submission met the necessary specification. Performance testing has been done according to FDA-recognized standards or guidance document: EN 1618:1997 Catheters Other than Intravascular Catheters - Test Methods For Common Properties, ASTM F640-12 Standard Test Methods for Determining Radiopacity for Medical Use, ASTM D412A:2015 A guide to Polymeric Geomembranes: A Practical Approach.
In addition, the biocompatibility of the devices has been confirmed in accordance with ISO 10993, and the company has conducted sterilization adoption validation in accordance with recognized industry standards. The RocaTub ureteral catheter has a validated shelf life of 2 years.

A list of the tests performed to support substantial equivalence is provided below:

- Sterilization Validation;
- Biocompatibility;
- Device verification and validation
- Transportation adoption Validation;
- Shelf life adoption Validation.

The results of these evaluations demonstrate that the RocaTub Ureteral Catheter are safe and effective when used in accordance with their intended use and labeling.

G. Comparison of Technological Characteristics:

The RocaTub Ureteral Catheters are substantially equivalent to Coloplast currently marketed the Ureteric Catheters, regarding to the intended use, design and sterilization process.

Product Name	**RocaTub Ureteral Catheter**	**Ureteric Catheters**
510(k) Number	K192183	K182122
Product Code	EYB	EYB
Regulation Name	Ureteral Catheter	Ureteral Catheter
Manufacturer	PROMEPLA SAM	Coloplast Corp
Intended Use	RocaTub catheters are intended for use during ureteral catherization, drainage, opacification of the upper urinary tract (retrograde ureteropyelography) and flushing procedures	The Ureteric Catheters for retrograde ureteropyelography are intended for injection of contrast medium or saline during endourological procedures
Diameter	From 4 Fr to 7 Fr	From 5 Fr to 7Fr
Disposable	YES	YES
Sterile	YES	YES
Stylet for ease of insertion	YES	YES
Suitable for use with a guidewire	YES	YES
Connection with a syringe	YES	YES
Material	Thermoplastic Polyurethane	Polyether block amide

Tip shape	Straight or open distal tip	Straight or open distal tip
Side eyes	With or without	With or without
Ink Marks	YES	YES
Hydrophilic coating	YES	NO
Type of sterilization	Ethylene oxide	Ethylene oxide

*Green Boxes means that the characteristics are the same between the subject device and the predicate.

H. Conclusion

Promepla SAM has demonstrated that the proposed RocaTub Ureteral Catheter are substantially equivalent to Coloplast currently marketed the Ureteric Catheters, cleared under premarket notification number K182122. The differences do not affect the performances and the safety of the patient as biocompatibility tests have been performed to ensure that the raw material used are biocompatible. An analysis of material sheets/safety data sheets has been performed as well as a risk analysis. Plus, the RocaTub Ureteral Catheter have a hydrophilic coating which when activated allow to insert more easily the device into the patient than the predicate device. So, the RocaTub Ureteral Catheter are safe and effective as the corresponding predicate device when used in accordance with their intended use and labeling.