March 12, 2018

Promepla SAM
Alexandre Bareille
Regulatory Affairs Manager
9 Avenue Albert II
Monaco, 98000
Monaco

Re: K173734
Trade/Device Name: RocaJJ Soft Stents
Regulation Number: 21 CFR§ 876.4620
Regulation Name: Ureteral Stent
Regulatory Class: II
Product Code: FAD
Dated: February 15, 2018
Received: February 20, 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Joyce M. Whang -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)*
K173734

Device Name
RocaJJ Soft Stents

Indications for Use *(Describe)*
The RocaJJ Soft Stents are used for temporary internal drainage from the ureteropelvic junction to the bladder. Ureteral stents have been used to relieve obstruction in a variety of benign, malignant, and post-traumatic conditions. The stents may be placed using endoscopic techniques.
The stents are not intended as a permanent indwelling devices, it is recommended that:
- The indwelling time not exceed 6 days when the device is used with the removal string;
- The indwelling time not exceed 365 days when the device is used without the removal string.
Target population: adults only (at least 22 years old)

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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
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	December 01, 2017

B. Device Name

Trade Name of Device:	RocaJJ Soft Stents
Common Name:	Stent, Ureteral
Regulation Number:	21 CFR 876.4620
Regulation Name :	Ureteral stent
Regulation Class :	II
Product Code :	FAD
Panel :	Gastroenterology/Urology
Official Contact Person:	Alexandre Bareille

C. Predicates Devices

N°	Product name	Manufacturer	510(k) number
1	Bard InLayOptima Ureteral Stent With Suture	Bard	K043193
2	Universa Soft Ureteral Stents and Stent Sets	Cook	K151051

D. Device Description:

The RocaJJ Soft Stents system is a set consisting of a tubular double pigtail stent made up of flexible radiopaque polyurethane, with a polypropylene-monofilament suture loop in order to facilitate the extraction of the ureteral stent.
The devices may include a pusher with a radiopaque tip, and a guidewire. Otherwise, these sets may include only a pusher.

The RocaJJ Soft Stents are from 4.8 to 8.0 Fr in diameter and from 24 to 30 cm in specified length.

E. Intended Use:

The RocaJJ Soft Stents are used for temporary internal drainage from the ureteropelvic junction to the bladder. Ureteral stents have been used to relieve obstruction in a variety of benign, malignant, and post-traumatic conditions. The stents may be placed using endoscopic techniques.
The stents are not intended as a permanent indwelling devices, it is recommended that:

- The indwelling time not exceed 6 days when the device is used with the removal string;
- The indwelling time not exceed 365 days when the device is used without the removal string.

Target population: adults only (at least 22 years old)

F. Technological Characteristics and Performance Data:

In support of this 510(k) premarket notification, Promepla SAM has conducted bench testing to demonstrate that RocaJJ Soft Stents 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, shelf life and transportation validation in accordance with recognized industry standards.
A list of the tests performed to support substantial equivalence is provided below:

- Sterilization Validation;
- Transportation Validation;
- Tensile strength;
- Ultimate elongation;
- Opening force of the retaining loops;
- Drainage capacity;
- Biocompatibility;
- Shelf life Validation.

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

G. Substantial Equivalence:

The RocaJJ Soft Stents are substantially equivalent to the Bard InLayOptima Ureteral Stent and to the Cook Universa Soft Stents in regard to intended use, design, materials and function.

Product Name	**RocaJJ Soft Stents**	**Bard InLayOptima Ureteral Stent with Suture**	**Universa Soft Ureteral Stents and Stent Sets**
510(k) Number	--	K043193	K151051
Product Code	FAD	FAD	FAD
Regulation Name	Ureteral Stent	Ureteral Stent	Ureteral Stent
Manufacturer	PROMEPLA SAM	C.R. Bard. Inc. Urological Division	Cook Incorporated (Cook)
Intended Use	The **RocaJJ Soft Stents** are used for temporary internal drainage from the ureteropelvic junction to the bladder. Ureteral stents have been used to relieve obstruction in a variety of benign, malignant, and post-traumatic conditions. The stents may be placed using endoscopic techniques. The stents are not intended as a permanent indwelling devices, it is recommended that: - The indwelling time not exceed 6 days when the device is used with the removal string; - The indwelling time not exceed 365 days when the device is used without the removal string.	The **Bard InLayOptima Ureteral Stent and Multi-Length Ureteral Stent** is indicated to relieve obstruction in a variety of benign, malignant and post-traumatic conditions in the ureter. These conditions include stones and/or stone fragments or other ureteral obstructions such as those associated with ureteral stricture, malignancy of abdominal organs, retroperitoneal fibrosis or ureteral trauma, or in association with ESWL. The stent may be placed using endoscopic surgical techniques or percutaneously using standard radiographic technique. It is recommended that the indwelling time not exceed 365 days. The stent is not intended as a permanent indwelling device.	The **Universa Soft Ureteral Stents and Stent Sets** aer used for temporary internal drainage from the ureteropelvic junction to the bladder. Ureteral stents have been used to relieve obstruction in a variety of benign, malignant, and post-traumatic conditions. The stents may be placed using endoscopic, percutaneous, or open surgical techniques.

The RocaJJ Soft Stents and its predicates have a similar intended use, diameter, length, indwelling period without the withdrawal string, sterility process, radiopaque properties, material, material-processing and design.

The RocaJJ Soft Stents have a shorter indwelling time with the withdrawal string than the Universa Soft Stent, which is more favorable.

RocaJJ Soft Stents pusher is made of Polyamide instead of HDPE for Bard InLay Optima, which is a more resistant material. Length of pusher is equivalent for 6/7/8Fr versions while 4.8Fr pusher is longer in RocaJJ Soft Stents, which is more favorable as it allows an easier handling by physician.
RocaJJ Soft Stents exist in a span of lengths from 24 to 30cm, which is narrower than predicate devices and address most of patients.

Guidewire interface is 0.035” for RocaJJ Soft Stents, while predicates allow a guidewire diameter up to 0.038”. Standard endoscopic procedures use 0.035” guidewires, while 0.038” guidewires are more commonly used in percutaneous procedures which are not included in RocaJJ Soft Stents intended use.

Hence, the RocaJJ Soft Stents are substantially equivalent to the predicates devices since the basic features and intended uses are the same.

The minor differences between RocaJJ Soft Stents and the predicate devices raise no new issues of safety and effectiveness.