March 10, 2022

Rocamed SAM
Tahiana Rasolofoniaina
Regulatory Affairs Specialist
9 Avenue Albert II
Monaco, Monaco 98000
Monaco

Re: K212868
Trade/Device Name: JFil Ureteral Stents, JFil Ureteral Stents ECO KIT
Regulation Number: 21 CFR 876.4620
Regulation Name: Ureteral stent
Regulatory Class: Class II
Product Code: FAD

Dear Tahiana Rasolofoniaina:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated January 26, 2022. Specifically, FDA is updating this SE Letter with corrected model numbers of your device as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Jessica K. Nguyen, Ph.D., OHT3: Office of GastroRenal, ObGyn, General Hospital and Urology Devices, Jessica.Nguyen@fda.hhs.gov.

Sincerely,

Jessica K. Nguyen -S

Jessica K. Nguyen, Ph.D.
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

January 26, 2022

Rocamed SAM
Tahiana Rasolofoniaina
Regulatory Affairs Specialist
9 Avenue Albert II
Monaco, Monaco 98000
Monaco

Re: K212868
Trade/Device Name: JFil® Ureteral Stents, JFil® ECO Kit
Regulation Number: 21 CFR§ 876.4620
Regulation Name: Ureteral Stent
Regulatory Class: II
Product Code: FAD
Dated: December 23, 2021
Received: December 29, 2021

Dear Tahiana Rasolofoniaina:

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,

Angel A. Soler-garcia -S

For
Jessica K. Nguyen, Ph.D.
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

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)*
K212868

Device Name
JFil® Ureteral Stents, JFil® ECO KIT

Indications for Use *(Describe)*
The JFil® Ureteral Stents are used for temporary internal drainage of the ureteropelvic junction.

The stents may be placed using endoscopic techniques.

The stents are not intended as permanent indwelling devices, it is recommended that the indwelling time does not exceed 14 days.

Target population: adults only (greater than 21 years of age).

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Food and Drug Administration
Office of Chief Information Officer
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PRAStaff@fda.hhs.gov

"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

1. Submitter Information

510 (k) submitter:	ROCAMED SAM
Address:	9 Avenue Albert II 98000 Monaco MONACO (Principality of)
Contact Person Name:	Tahiana Rasolofoniaina
Contact Title:	Regulatory Affairs Specialist
Contact Person's email:	tr@promepla.com
Contact Person's Number:	(+377) 979-842-44
Preparation date:	January 25, 2022

2. Device Information

Trade Name of the Device:	JFil® Ureteral Stents, JFil® ECO KIT
Common Name	Ureteral Stent
Classification Name:	Stent, Ureteral
Classification Regulation:	21 CFR 876.4620
Device Class:	II
Review Panel	Gastroenterology/Urology
Product Code	FAD

3. Predicate Devices

510(k) number	K030503	K173734
Owner	Boston Scientific Corp.	Promepla SAM
Trade name of the Device	Polaris Loop Ureteral Stents	RocaJJ Soft Stents
Classification Name	Stent, Ureteral	Stent, Ureteral
Regulation Classification	21 CFR 876.4620	21 CFR 876.4620
Device Class	II	II
Panel	Gastroenterology/Urology	Gastroenterology/Urology
Product Code	FAD	FAD

Both predicate devices have not been subjected to a design-related recall.

4. Device Description

The JFil® Ureteral Stents consist of a tube-like device that is inserted into the ureter to allow the passage of the urine in the treatment of ureteral injuries and ureteral obstructions. This polyurethane stent has a single loop on the proximal tip and a polypropylene-monofilament surgical thread on the distal tip. JFil stents are 6.0 or 7.0 French (Fr) in diameter and 8 or 16 cm in specified length. The stent is provided with a 63 cm length pusher and may include a Nitinol Guidewire in the kit. The pusher consists of a radio-opaque ring connected to a tubing, and is intended to allow pushing, placing, and releasing the stent inside the patient. This stents can only be used by trained professionals in a clinic or hospitals environment. The JFil Ureteral Stents are sterile and for single use only. The stents are also available in ECO-kits which do not include a guidewire. The stents can be removed cystoscopically by gently pulling on the surgical thread.

The models are described in the table below:

Designation	Ø (Fr)	Length (cm)	Presence of guide	Designation of the product
ROJV0608ST	6	8	Yes	JFil® – Ureteral Stent – 6Fr ; 8cm
ROJV0616ST	6	16	Yes	JFil® – Ureteral Stent – 6Fr ; 16cm
ROJV0708ST	7	8	Yes	JFil® – Ureteral Stent – 7Fr ; 8cm
ROJV0716ST	7	16	Yes	JFil® – Ureteral Stent – 7Fr ; 16cm
ROJV5708ST	7	8	No	JFil® ECO KIT – Ureteral Stent – 7Fr ; 8cm
ROJV5716ST	7	16	No	JFil® ECO KIT – Ureteral Stent – 7Fr ; 16cm

5. Intended Use

The JFil® Ureteral Stents are used for temporary internal drainage of the ureteropelvic junction.

The stents may be placed using endoscopic techniques.

The stents are not intended as permanent indwelling devices, it is recommended that the indwelling time does not exceed 14 days.

Target population: adults only (greater than 21 years of age).

6. Comparison of The Technological Characteristics with Predicate Devices:

Device & Predicate Trade name (Applicant)	**Device under evaluation JFil® Ureteral Stents** (Rocamed)	**Primary Predicate - K030503 Polaris™ Loop Ureteral Stents** (Boston Scientific)	**Secondary Predicate - K173734 RocaJJ Soft Ureteral Stents** (Promepla)
Regulation Number	876.4620	876.4620	876.4620
Regulation Name	Stents, Ureteral	Stents, Ureteral	Stents, Ureteral
Product Code	FAD	FAD	FAD
Classification	Class II	Class II	Class II
Stent Type	Single J Stent	Single J Stent	Double J Stent

Intended Use Conditions	-Surgical suite in a hospital environment - Medical facilities -Under aseptic conditions (clothing, sterile surgical gloves, and a controlled atmosphere)		The use conditions for the device are a surgical suite in a hospital environment. Ureteral stents are handled by surgeons under aseptic conditions (clothing, sterile surgical gloves, and a controlled atmosphere). They will be placed for a length of time specified by the urologist surgeon.		- Surgical suite in a hospital environment - Medical facilities - Under aseptic conditions (clothing, sterile surgical gloves, and a controlled atmosphere)
Prescription of use	Sale by or on the order of a physician		Sale by or on the order of a physician		Sale by or on the order of a physician
Reuse Status	Single Use		Single Use		Single Use
Sterilization	Ethylene oxide (EO)		Ethylene oxide (EO)		Ethylene oxide (EO)
Size (Fr)	6/7		5/6/7/8		4,8/6/7/8
Length (cm)	8	16	16	10/12/14/18 /20/22/ 24/26/28/30	24/26/28/30
Stent type	Simple J		Simple J		Double J
Renal loop	Pigtail loop		Pigtail loop		Pigtail loop
Bladder loop	Suture thread		Suture loop		Pigtail loop
Suture material	Polypropylene		Polypropylene		Polypropylene
Guidewire Compatibility	0.035”		0.038”		0.035”
Ink Mark	No		Yes		Yes
Shelf-life	3 Years		Unknown		3 Years
Radiopacity	Yes		Yes		Yes
Placement	Placed using endoscopic techniques		placement endoscopically or fluoroscopically		Placed using endoscopic techniques
Indwelling time	14 days		14 days		6 days

As evidenced by the above table, both the subject and the predicate devices have the same intended use, but the subject and predicate devices have different technological characteristics. However, these differences do not raise different questions of safety or effectiveness and the testing mentioned below showed that the subject is substantially equivalent with the predicates.

7. Performance Data

Performance Data – Bench

In support of this premarket notification, Rocamed conducted the following bench performance testing –

- Drainage capacity, Per ASTM F623-99, “Standard Performance Specification for Foley Catheter”
- Curl strength
- Tensile and elongation/yield strength
- Shelf life validation

All bench testing results confirmed that the products described in this submission met the necessary specification.

Biocompatibility Testing

Biocompatibility of the subject stents was confirmed per ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process”. The device met the requirements.

8. Conclusion

Based on the information presented in this submission, it can be concluded that the subject device is substantially equivalent to the predicates.