



Food and Drug Administration
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February 9, 2016

Promepla SAM
Alexandre Bareille
Asst. Quality Manager - Regulatory Affairs
9 Avenue Prince Albert II
98000 Monaco

Re: K152278
Trade/Device Name: ENDOFLOW II - Irrigation, Warming and Suction System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: OCX
Dated: December 22, 2015
Received: December 28, 2015

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


Herbert P. Lerner -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

Indications for Use

510(k) Number (if known)

K152278

Device Name

ENDOFLOW II - Irrigation, Warning and Suction System

Indications for Use (Describe)

The ENDOFLOW® II Irrigation, Warming and Suction System is indicated for use in medical facilities under direction of a trained physician during endo-urology, hysteroscopy and laparoscopy procedures in order to fill and/or wash different operating cavities.

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.

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Submitter:
Promepla SAM

ENDOFLOW® II
Traditional 510(k)

510 (k) Summary

A. Submitter Information

Submitter's Name: PROMEPLA SAM
Address 9 Avenue Prince Albert II
98000 Monaco
MONACO (Principality of)
Contact Person Alexandre Bareille
Contact Person's email: alb@promepla.com
Contact Person's Number (377) 97984244
Contact Person's Fax (377) 92056150
Submission date August 05, 2015

B. Device Name

Trade Name of the Device: ENDOFLOW II – Irrigation, Warming and Suction System
Models: MEN01US: ENDOFLOW® II single chamber (120V 60Hz, 100V 50/60Hz)
MEN02PUS: ENDOFLOW® II double chamber with aspiration pump (120V 60Hz, 100V 50/60Hz)
Common Name: ENDOFLOW II
Device Class: 2
Classification Name(s): Gastroenterology/Urology
Product Code: OCX
Classification Regulation: 21 CFR 876.1500
Official Contact Person: Alexandre Bareille

C. Predicates Devices

N°	Product name	Manufacturer
1	ENDOGATOR ADVANTAGE IRRIGATION PUMP	BYRNE MEDICAL, INC.
2	NORMOFLO IRRIGATION FLUID WARMER	SMITHS MEDICAL ASD, INC.
3	FMS DUO®	FUTURE MEDICAL SYSTEMS, INC

Submitter:
Promepia SAM

ENDOFLOW® II
Traditional 510(k)

D. Device Description:

The ENDOFLOW® II System includes the electro medical device and a full range of disposables dedicated to perform endoscopic procedures for Endo-urology, Hysteroscopy and Laparoscopy surgery.

The ENDOFLOW® II System is a complete fluid management system permitting, all-in-one, the control of the Irrigation, the temperature of the fluid and the suction.

The ENDOFLOW® II permits a continuous and non-pulsating liquid flow to inflate and clean the surgical field and to improve the surgeon's visibility. With the ENDOFLOW® II system, the indicated pressure on the machine is identical to the pressure in the cavity.

The ENDOFLOW® II heats and maintains the fluid bag at 38°C during the entire procedure. The user can disable this function.

The ENDOFLOW® II, in its double chamber version, MEN02PUS, offers an aspiration system that can be activated with the touch screen and/or a footswitch.

E. Intended Use:

The ENDOFLOW® II Irrigation, Warming and Suction System intended to be used in medical facilities under direction of a trained physician during endo-urology, hysteroscopy and laparoscopy procedures in order to fill and/or wash different operating cavities.

F. Technological Characteristics Summary:

Irrigation is obtained by compressed medical air that permits to pressurize the liquid bag. The pressurization is conducted in a closed tank exposing the liquid bag to an adjusted air pressure.

The ENDOFLOW® II includes a thermostatic heater that maintains the liquid bag to 38°C during the procedure. It permits to maintain the patient's body temperature during the procedure. It also reduces the condensation effect in the endoscope. The user can disable this function by the touch screen.

On the double chambers MEN02PUS, the aspiration system is performed by a peristaltic-roller pump. The system is directly managed by the user with the touch screen and/or the footswitch.

The requirements for fluid management are adapted to the types of surgical procedures (Endo-urology, Hysteroscopy and Laparoscopy).

ENDOFLOW® II includes RFID technology that helps the user preselecting the appropriated parameters when the disposable is detected by the electro-medical device and preventing any reuse of the disposable. There is a range of disposables dedicated to each different intended surgical application.

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ENDOFLOW® II
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G. Substantial Equivalence:

Product Name	ENDOFLOW II Irrigation, Warming and Suction System Models MEN01US & MEN02PUS	NORMOFLO IRRIGATION FLUID WARMER, MODEL H-1129	ENDOGATOR ADVANTAGE IRRIGATION PUMP MODEL EGA-500	FMS DUO®
510(k) Number		K072080	K113119	K954465
Product Code	OCX	LGZ	OCX	HRX
Classification Name	Endoscopic Irrigation/Suction System	Warmer, Thermal, Infusion Fluid	Endoscopic Irrigation/Suction System	Arthroscopy
Manufacturer	PROMEPLA SAM	SMITHS MEDICAL ASD, INC.	BYRNE MEDICAL, INC.	FUTURE MEDICAL SYSTEMS, INC
Intended Use	The ENDOFLOW® II Irrigation, Warming and Suction System intended to be used in medical facilities under direction of a trained physician during endo-urology, hysteroscopy and laparoscopy procedures in order to fill and/or wash different operating cavities.	NORMOFLO Irrigation Fluid Warmer <i>NORMOFLO Irrigation Fluid Warmer</i> The Level 1 NORMOFLO® Irrigation Fluid Warmer is designed for use by trained medical personnel for in-line warming of irrigation fluids.	The EndoGator Advantage Irrigation Pump EGA-500 is indicated for endoscopic irrigation for use with washing catheters, integra endoscope water jet channels and endoscope working channels.	The FMS DUO®+ is intended to be used in arthroscopic surgery in the following joints: shoulder, knee, ankle, elbow, wrist, hip.
Main Functions	Irrigation	Similar	Different	Different
	Warming	Different	Similar	N/A
	Suction	Different	N/A	Similar

ENDOFLOW® II is substantially equivalent to the predicate devices since the basic features and intended uses are the same.

The minor differences between ENDOFLOW® II and the predicate devices raise no new issues of safety and effectiveness.

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ENDOFLOW® II
Traditional 510(k)

H. Performance Data:

Performance testing have been executed to validate the performance and safety of the devices.

Verification and validation activities were conducted to establish the performance and safety characteristics of the ENDOFLOW® II. The results of these activities demonstrate that the ENDOFLOW® II is safe and effective when used in accordance with its intended use and labeling.