510(k) Summary

JAN 2 4 2013

Date Prepared: January 9, 2013

Submitter Information:

Submitter's Name/Address	Contact Person
Medafor 2700 Freeway Boulevard, Suite 800 Minneapolis, MN 55430 Telephone: 763-231-8201 Fax: 763-571-1035	Melissa Young, Senior Regulatory Affairs Specialist

Device Information:

Trade Name	MEDAFOR DIRECT Gas-Assisted Application System - MEDAFOR DIRECT™ Pressurized Gas Regulator and DIRECT Kit™ Gas-Assisted Applicator
Common Name	Gas Regulator and Gas-Assisted Spray Kit
Classification Name	Endoscope and Accessories
Product Code	GCJ
Regulation	876.1500
Panel	General and Plastic Surgery

Performance Standards:

No performance standards applicable to this product have been developed under Section 514 of the Act.

Predicate Device:

Predicate Device	Manufacturer	510(k) No.
FibriJet Air Assisted Endoscopic Applicator	Micromedics, Inc.	K042834

Device Description:

The MEDAFOR DIRECT Gas-Assisted Application System is intended to be used on patients undergoing surgery including laparoscopic/endoscopic procedures. The gas-assisted applicator kit and regulator are provided to assist the user in the application of powdered hemostatic agents to bleeding tissue in surgical procedures including laparoscopic/endoscopic surgeries, using a 5 mm or larger trocar.

The following table describes the MEDAFOR DIRECT Gas-Assisted Application System that is intended to be commercially marketed. The device system consists of the following components in the following packaging configurations:

MEDAFOR DIRECT Configurations and Components		
No.	**Packaging Configuration**	**Components Included**
1.	Regulator Kit: Packaged in a corrugated box	Gas Regulator
		Foot pedal
2.	Gas Assisted Applicator Kit is supplied as a sterile, single use kit packaged in a preformed PETG tray and Tyvek®[1] lid	Tubing set
		Adapter Handle
		FlexiTip XL-R rigid applicator

The gas regulator and foot pedal are supplied separately as non-sterile, reusable components. The Gas-Assisted Applicator kit is provided as a sterile, disposable unit, consisting of the tubing set, applicator adapter and a single unit of FlexiTip XL-R applicator. These disposable components are kitted together in a preformed tray and Tyvek® lid and terminally sterilized by ethylene oxide.

Intended Use/Indications for Use:

The device is intended to assist the delivery of a powdered hemostatic agent to the treatment site in surgical procedures including endoscopic surgeries, using a 5 mm or larger trocar.

Summary of Non-Clinical Testing:

The MEDAFOR DIRECT Gas-Assisted Application System underwent mechanical, performance, and biocompatibility assessments to verify that the device functions in a safe and effective manner.

The mechanical tests performed on the MEDAFOR DIRECT Gas-Assisted Application System include:

Critical Parameter	Mechanical Test
Device Interface Compatibility	Trocar luer compatibility
	Trocar 5 mm cannula compatibility
	CO_2 tank connector compatibility
Device Delivery	Container content delivery of hemostatic agent in powdered form
	Delivery Control (location and area)
	Blood clearing from site
	System Leak Testing (Maintaining Pneumoperitinum)
Device Functionality	Pressure Monitoring
	Flow Control & Monitoring
	System Performance Testing (Internal device component compatibility (gas tank tubing to regulator/tubing to adapter/adapter to FlexiTip XL-R)

[1] Tyvek® is a registered trademark of DuPont

Critical Parameter	Mechanical Test
	System Verification Test in Swine: Performed as intended under simulated conditions to confirm output meets input

All tests met acceptance criteria. These results provide assurance that the device has been designed and evaluated to assure conformance to the requirements for its intended use.

Substantial Equivalence Comparison

The MEDAFOR DIRECT Gas Assisted Application System is substantially equivalent to the predicate device based on a comparison of the indications for use and the technological characteristics. The technological characteristics include design configuration, materials, method of sterilization, compatibility with the same ancillary devices (such as a standard 5 mm trocar) and method of operation.

While the subject and predicate device are intended to deliver materials to the patient during endoscopic surgery, they differ in the types of material to be delivered. The predicate device is intended to apply two nonhomogeneous liquids, while the subject device delivers a powder hemostat to the treatment site. However, when both devices are activated, the compressed gas fluidizes the liquid and powdered hemostat in the same manner, forcing them into an air stream in the form of a spray when exiting the applicator system.

Both subject and predicate devices are made of stainless steel and biosafe polymer materials and are terminally sterilized by ethylene oxide.

Both systems include components consistent with that used in endoscopic gas-assisted systems (regulator, footswitch, applicator/tubing set), however the applicator tubing set design and connections differ. The predicate applicator is designed as a dual path system that allows connection of two syringes by luer lock at the distal end. At the proximal end, the applicator is attached by threaded connection to the Replaceable tips. In contrast, the subject applicator has a simpler single path design that connects to a hemostatic powder container by friction fit at the distal end and does not require any attachment at the proximal end. Both device tubing sets attach to the gas supply by luer lock connections. The testing performed confirms that the MEDAFOR DIRECT Gas- Assisted Application System does will perform as intended, safely and effectively.

Conclusion

Based on the results from the bench and animal testing performed and the substantial equivalence comparison, the MEDAFOR DIRECT Gas-Assisted Application System does not raise new questions of safety and effectiveness when compared to the legally marketed predicate device and is, therefore, substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Medafor, Incorporated
% Ms. Melissa Young
Senior Regulatory Affairs Specialist
2700 Freeway Boulevard, Suite 800
Minneapolis, Minnesota 55430

January 24, 2013

Re: K123325
Trade/Device Name: MEDAFOR DIRECT Gas-Assisted Application System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: January 09, 2013
Received: January 10, 2013

Dear Ms. Young:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): ___K123325_____

Device Name: **MEDAFOR DIRECT Gas-Assisted Application System**

Indications for Use:

The device is intended to assist the delivery of a powdered hemostatic agent to the treatment site in surgical procedures including endoscopic surgeries, using a 5 mm or larger trocar.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Neil R Ogden
2013.01.18 14:06:00 -05'00'

(Division Sign-Off)
Division of Surgical Devices
510(k) Number ____K123325____

Concurrence of CDRH, Office of Device Evaluation (ODE)