DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

September 9, 2014

Fujifilm Medical System, USA, Inc.
Mary K. Moore
Senior Director, Regulatory Affairs and Quality Assurance
10 High Point Drive
Wayne, NJ 07470

Re: K133976
Trade/Device Name: Fujifilm Endoscopic CO2 Regulator GW-100
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FCX
Dated: August 14, 2014
Received: August 15, 2014

Dear Mary K. Moore,

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Benjamin R. Fisher -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133976

Device Name
Fujifilm Endoscopic CO2 Regulator GW-100

Indications for Use *(Describe)*
This product is intended to supply CO2 gas and feed water to clean lenses in the gastrointestinal tract when used as an accessory with Fujifilm's endoscopy system.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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FUJIFILM

510(k) Summary

Date: September 8, 2014

Submitter's Information:

FUJIFILM Medical Systems U.S.A., Inc.
10 High Point Drive
Wayne, NJ 07470 USA
FDA Establishment Registration Number: 2431293

Contact Person:

Mary K. Moore
Senior Director, Regulatory Affairs and Quality Assurance
Telephone: (973) 686-2498
Facsimile: (973) 686-2616
E-Mail: mkmoore@fujifilm.com

Identification of the Subject Device:

Proprietary/Trade Name: Fujifilm Endoscopic CO_2 Regulator GW-100
Common Name: Endoscopic CO_2 Regulator
Device Class: Class II
Review Panel: Gastroenterology/Urology
Classification Information:

Classification Name	CFR Section	Product Code
Insufflator, Automatic Carbon-Dioxide for Endoscope	21 CFR 876.1500	FCX

I. INDICATIONS FOR USE

The Fujifilm Endoscopic CO_2 Regulator GW-100 is intended to supply CO_2 gas and feed water to clean lenses in the gastrointestinal tract when used as an accessory with Fujifilm's endoscopy system.

II. DEVICE DESCRIPTION

The Fujifilm Endoscopic CO_2 Regulator GW-100 supplies CO_2 gas to insufflate the gastrointestinal tract and water to wash the endoscope lens during an examination. The GW-100 is similar to Olympus' XECR-2 Endoscopic Insufflation Unit. The scientific fundamental technology and operating principle of the subject and predicate devices are similar. Both devices utilize a solenoid/decompression valve mechanism to dispense CO_2. CO_2 can either be supplied from a CO_2 gas cylinder or from a facility's main CO_2 supply.

The GW-100 can be used with any Fujnon/Fujifilm gastrointestinal endoscope, Fujinon/Fujifilm Video Processor/Light Source system, video monitor, footswitch, cart, endoscopic accessories, electrosurgical unit and other peripheral devices used for endoscopy.

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III. SUMMARY OF NON-CLINICAL STUDIES

The Fujifilm Endoscopic CO_2 Regulator GW-100 has been subjected to and passed electrical safety, EMC and software testing requirements.

Fujifilm Endoscopic CO_2 Regulator GW-100 was evaluated in accordance with the following voluntary standards as applicable to the device.

- IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-1 Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems
- IEC 60601-2-18 Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
- IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic Compatibility - Requirements and tests
- IEC 60601-1-4 Medical Electrical Equipment Safety Standards Series
- IEC 62304 Medical device software — Software life cycle processes
- ISO 10993-1* Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- ISO10993-5 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
- ISO10993-10 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization

*Evaluation to ISO 10993-1was conducted for indirect patient contact materials for the Water Tank WT-04G.

Software validation was performed. The device software is considered a "Minor Level of Concern."

The reprocessing instructions were validated.

No clinical testing was conducted.

IV. SUBSTANTIAL EQUIVALENCE

Fujifilm Endoscopic CO_2 Regulator GW-100 is substantially equivalent to the following device:

Subject Device	Predicate Device	510(k) #
Fujifilm Endoscopic CO_2 Regulator GW-100	Olympus Endoscopic Insufflation Unit, Model XECR-2	K063786

V. CONCLUSION

Fujifilm Endoscopic CO_2 Regulator GW-100 is substantially equivalent to the legally marketed device and conforms to applicable medical device safety and performance standards.