



May 25, 2018

FUJIFILM Corporation
% Jeffrey Wan
Specialist, Regulatory Affairs
FUJIFILM Medical Systems U.S.A., Inc.
40 Boroline Road
Allendale, New Jersey 07401

Re: K180711
Trade/Device Name: FUJIFILM Endoscopic CO2 Regulator GW-100
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FCX
Dated: April 27, 2018
Received: April 27, 2018

Dear Jeffrey Wan:

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

Indications for Use

510(k) Number (if known)

K180711

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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VII. 510(K) SUMMARY**510(k) SUMMARY****FUJIFILM Endoscopic CO₂ Regulator GW-100****Submitter's Information:**

FUJIFILM Corporation
798 Miyanodai Kaisei-Machi
Ashigarakami-Gun, Kanagawa, 258-8538, Japan
FDA Establishment Registration Number: 3001722928

Contact Person:

Jeffrey Wan
Specialist, Regulatory Affairs
Fujifilm Medical Systems U.S.A., Inc.
Endoscopy Division
Telephone: (973) 709-2219
Facsimile: (973) 686-8818
E-Mail: jeffrey.wan@fujifilm.com

Date Prepared: March 19, 2018

Identification of the Proposed 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: | Endoscope and accessories, 21 C.F.R. § 876.1500 |
| Product Code: | FCX |

Predicate Device:

Fujifilm Endoscopic CO₂ Regulator GW-100, Fujifilm Medical Systems U.S.A, K133976

Reference Device:

FUJIFILM Water Tank WT-603, FUJIFILM Corporation, K172916

Intended Use / Indications for Use:

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.

Device Description:

FUJIFILM Endoscopic CO₂ Regulator GW-100 supplies CO₂ gas to insufflate the gastrointestinal tract. The GW-100 supplies water to wash the endoscope lens during an examination.

FUJIFILM Endoscopic CO₂ Regulator GW-100 is comprised of the following components: Main Unit, Water Tank, and Gas Tube. The Main Unit utilizes a solenoid/decompression valve mechanism to dispense CO₂ from the Water Tank via the Gas Tube and the air/water channel in the endoscope into the body cavity. The Main Unit also supplies sterile water from the Water Tank via the air/water channel in the endoscope.

Technological Characteristics:

A comparison of the technological characteristics between the modified and predicate devices is provided in the table below. The only modification to the proposed GW-100 is the addition of WT-604G and AW-604G as optional accessories. WT-604G is a class II accessory; AW-604G is a class I accessory.

| | Proposed Device | Predicate Device |
|---|---|---|
| Device name | GW-100 | GW-100 |
| Common name | Same as K133976 | Insufflator, Automatic Carbon-Dioxide For Endoscope |
| Manufacturer | Same as K133976 | FUJIFILM Corporation |
| 510(k) number | Same as K133976 | K133976 |
| Intended Use/Indications for Use | This product 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. | This product 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. |
| Power supply | Same as K133976 | 100-240VAC 50/60Hz |
| Current consumption | Same as K133976 | 0.3A |
| Dimensions | Same as K133976 | W145 x H170 x D390 mm |
| Mass | Same as K133976 | 7kg |
| Gas supply method | Same as K133976 | Supply by carbon dioxide gas cylinder or medical gas pipeline system |
| Gas supplied | Same as K133976 | CO ₂ |
| Max pressure feed | Same as K133976 | 65kPa |
| Feeding method | Same as K133976 | Decompression valve |
| Feeding flow setting | Same as K133976 | Normal, Low |
| Feeding pressure indicator | Same as K133976 | Six level indication |
| Compatible Water Tank | WT-04G(standard accessory) WT-604G(optional accessory) | WT-04G(standard accessory) |
| Compatible Gas/Water Valve | AW-500(standard accessory) AW-604G(optional accessory) | AW-500(standard accessory for applicable endoscopes) |

| | | |
|-------------------------------------|---------------------------------|---------------------------------|
| Compatible Gas Tube | Same as K133976 | CT-11G |
| Electrical Safety Compliance | ANSI/AAMI ES60601-1 Edition 3.1 | ANSI/AAMI ES60601-1 Edition 3.0 |

Substantial equivalence was determined based on the performance testing described below.

Performance Data:

Electrical safety testing was conducted on the proposed device GW-100 using the following consensus standards: ANSI/AAMI ES60601-1:2005+AMD1:2012 CSV, IEC 60601-1-2:2007, IEC 60601-1-6:2013, and IEC 60601-2-18:2009.

The proposed optional accessory WT-604G was adopted into biocompatibility testing conducted on the reference device WT-603 using the following consensus standards: ISO 10993-1:2009, ISO 10993-5:2009, and ISO 10993-10:2010.

The proposed device GW-100 was adopted into software testing conducted on the predicate device GW-100 according to the consensus standard IEC 62304:2006.

The proposed optional accessory WT-604G was adopted into cleaning, high-level disinfection, and sterilization validation testing conducted on the reference device WT-603 in accordance with the FDA guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" (March 17, 2015).

Fujifilm conducted the following performance testing on the proposed device GW-100 to ensure that the modified device performs equivalently to the predicate device:

- CO₂ gas supply
- Water supply

In all cases, the device met the pre-defined acceptance criteria for the test.

Substantial Equivalence:

The company's GW-100 has the same intended use as the previously cleared predicate GW-100 (K133976). In addition, the proposed device GW-100 has the same intended use, indications for use, technological characteristics, and principles of operation as its predicate. Although there is a minor difference between the proposed device and its predicate device, namely the addition of compatible accessories, this difference does not raise new or additional questions of safety or effectiveness of the proposed device. Thus, the proposed device GW-100 is substantially equivalent to its predicate device.

Conclusions:

The modified GW-100 is substantially equivalent to the predicate GW-100 and conforms to applicable medical device safety and performance standards.