September 10, 2021

FUJIFILM medwork GmbH
% Jeffrey Wan
Manager, Regulatory Affairs
FUJIFILM Medical Systems U.S.A., Inc.
81 Hartwell Avenue, Suite 300
Lexington, MA 02421

Re: K210625
Trade/Device Name: JAZZ Suction Valve, JAZZ Air/Water Valve, JAZZ Forceps Valve
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: ODC, FDF
Dated: August 6, 2021
Received: August 9, 2021

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. 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,

Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K210625

Device Name
JAZZ Suction Valve, JAZZ Air/Water Valve, JAZZ Forceps Valve

Indications for Use *(Describe)*
The JAZZ Disposable Valve Kit is comprised of the JAZZ Suction Valve, JAZZ Air/Water Valve, JAZZ Forceps Valve.

The JAZZ Suction Valve is intended to control the suction function (aspiration of air and fluids) of a FUJIFILM gastrointestinal endoscope during endoscopy procedures.

The JAZZ Air/Water Valve is intended to control air of a FUJIFILM gastrointestinal endoscope for insufflations and water delivery (for distal lens cleaning) during endoscopy procedures.

The JAZZ Forceps Valve is intended to facilitate passage of an endotherapy device, to prevent a leak or backflow of air and/or fluids, and to enable the suction function of a FUJIFILM gastrointestinal endoscope.

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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510(k) SUMMARY
FUJIFILM medwork GmbH
JAZZ Disposable Valve Kit

Date: August 6, 2021

Submitter's Information:
FUJIFILM medwork GmbH
Medworkring 1
91315 Höchstadt, Germany

Contact Person:
Jeffrey Wan
Manager, Regulatory Affairs
Telephone: (201) 675-8947
E-Mail: jeffrey.wan@fujifilm.com

Identification of the Proposed Device:

Device Name: JAZZ Suction Valve, JAZZ Air/Water Valve, JAZZ Forceps Valve
Common Name: Endoscope Channel Accessory
Device Class: Class II
Classification Number: 21 C.F.R. § 876.1500
Classification Name: Endoscope and accessories Device
Panel: Gastroentereology/Urology
Product Codes: ODC, FDF

Predicate Devices:

- DEFENDO Disposable Suction Valve Model 100305 (K102581)
- DEFENDO Disposable Air/Water Valve Model 100304 (K102409)
- DEFENDO Disposable Biopsy Valve Model 100301 (K090851)

Intended Use / Indications for Use

The JAZZ Disposable Valve Kit is comprised of the JAZZ Suction Valve, JAZZ Air/Water Valve, JAZZ Forceps Valve.

The JAZZ Suction Valve is intended to control the suction function (aspiration of air and fluids) of a FUJIFILM gastrointestinal endoscope during endoscopy procedures.

The JAZZ Air/Water Valve is intended to control air of a FUJIFILM gastrointestinal endoscope for insufflations and water delivery (for distal lens cleaning) during endoscopy procedures.

The JAZZ Forceps Valve is intended to facilitate passage of an endotherapy device, to prevent a leak or backflow of air and/or fluids, and to enable the suction function of a FUJIFILM gastrointestinal endoscope.

Device Description

The JAZZ Disposable Valve Kit is comprised of the JAZZ Suction Valve, Air/Water Valve, and Forceps Valve. These devices are intended for single-use and are supplied sterile, eliminating the need for manual cleaning and reprocessing. These valves are designed to be attached to the corresponding port of a FUJIFILM G7 gastrointestinal endoscope. The air/water valve can be activated to control air and water flow, while the suction valve can be activated to aspirate excess fluids or other debris. The forceps valve forms a tight seal with the biopsy port to prevent leakage of biomaterial, provide easy passage of endotherapy devices, and support thesuction function.

Comparison of Technological Characteristics

A comparison of technological characteristics between the JAZZ Disposable Valve Kit and the DEFENDO disposable valves is provided below:

	JAZZ Suction Valve	**DEFENDO Disposable Suction Valve 100305**	**Substantial Equivalence**
510(k) number	To be assigned	K102581	
Product Code	ODC	ODC, FDF	Similar
Regulation No.	21CFR § 876.1500	21CFR § 876.1500	Identical
Classification	2	2	Identical
Manufacturer	FUJIFILM medwork GmbH	Byrne Medical	
Supplied Sterile	Yes	Yes	Identical
Sterile method	EO	EO	Identical
Single use	Yes	Yes	Identical
Compatibility	FUJIFILM G7 Series GI Endoscopes	Olympus and Pentax 90 Series GI Endoscopes	Similar
Indications for Use	The JAZZ Suction Valve is intended to control the suction function (aspiration of air and fluids) of a FUJIFILM gastrointestinal endoscope during endoscopy procedures.	The DEFENDO Disposable Suction Valve is intended to be used to control the suction function of an endoscope during a GI endoscopic procedure.	Identical
Packaging	Suction, Air/Water, and Forceps Valves are housed in a single tray and sealed with a Tyvek sheet.	Suction and air/water valves are housed in a single tray and packaged in a sealed Tyvek pouch.	Similar

	JAZZ Air/Water Valve	**DEFENDO Disposable Air/Water Valve 100304**	**Substantial Equivalence**
510(k) number	To be assigned	K102409	
Product Code	ODC	ODC, FDF	Similar
Regulation No.	21CFR § 876.1500	21CFR § 876.1500	Identical
Classification	2	2	Identical
Manufacturer	FUJIFILM medwork GmbH	Byrne Medical	
Supplied Sterile	Yes	Yes	Identical
Sterile method	EO	EO	Identical
Single use	Yes	Yes	Identical
Compatibility	FUJIFILM G7 Series GI Endoscopes	Olympus and Pentax 90 Series GI Endoscopes	Similar
Indications for Use	The JAZZ Air/Water Valve is intended to control air of a FUJIFILM gastrointestinal endoscope for insufflations and water delivery (for distal lens cleaning) during endoscopy procedures.	The Single Use Air/Water Valve is intended to be used to control the air/water function on an endoscope during a GI endoscopic procedure.	Identical
Packaging	Suction, Air/Water, and Forceps Valves are housed in a single tray and sealed with a Tyvek sheet.	Suction and air/water valves are housed in a single tray and packaged in a sealed Tyvek pouch.	Similar

	JAZZ Forceps Valve	**DEFENDO Disposable Biopsy Valve Model 100301**	**Substantial Equivalence**
510(k) number	To be assigned	K090851	
Product Code	ODC	ODC	Identical
Regulation No.	21CFR § 876.1500	21CFR § 876.1500	Identical
Classification	2	2	Identical
Manufacturer	FUJIFILM medwork GmbH	Byrne Medical	
Supplied Sterile	Yes	Yes	Identical
Sterile method	EO	EO	Identical
Single use	Yes	Yes	Identical
Compatibility	FUJIFILM G7 Series GI Endoscopes	Olympus and Fujifilm GI Endoscopes	Similar

Indications for Use	*The JAZZ Forceps Valve is intended to facilitate passage of an endotherapy device, to prevent a leak or backflow of air and/or fluids, and to enable the suction function of a FUJIFILM gastrointestinal endoscope.	The Single Use Biopsy Valve is intended for covering the endoscope biopsy port during an endoscopy procedure. The Single Use Biopsy Valve provides access for endoscopic device passage and exchange, helps maintain sufflation, and minimizes leakage of biomaterial from the biopsy port throughout the endoscopic procedure.	Identical
Packaging	Suction, Air/Water, and Forceps Valves are housed in a single tray and sealed with a Tyvek sheet.	Suction and air/water valves are housed in a single tray and packaged in a sealed Tyvek pouch.	Similar

Performance Data

Biocompatibility of the subject device was evaluated using the following consensus standards: ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-7:2008, ISO 10993-10:2010. Biocompatibility testing was performed in accordance with FDA's guidance, "Use of International StandardISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process,'" published June 16, 2016.

Sterility of the subject devices was evaluated using the following consensus standards: ISO 11135:2014 and ISO 11607-1:2019.

The JAZZ Air/Water Valve was validated for its efficiency in preventing backflow to the proximal irrigation system as defined by the FDA Guidance, "Mitigating the Risk of Cross-Contamination from Valves and Accessories Used for Irrigation Through Flexible Gastrointestinal Endoscopes" published November 29, 2016.

Spring force testing was performed to evaluate the springs used in the subject devices.

The subject devices met performance specifications in the following additional non-clinical tests:

Suction Valve
- Suction pressure
- Tightness
- Functional life
- Compatibility with endoscope

Air/Water Valve
- Insufflation pressure

- Flushing pressure
- Tightness
- Functional life
- Compatibility with endoscope

Forceps Valve

- Tightness
- Compatibility with endoscope
- Compatibility with endoscopic instruments
- Ease of use

Conclusions

The subject device JAZZ Disposable Valve Kit shares the same intended use and substantially similar indications to the predicate devices. Bench testing demonstrates that the subject device is as safe and effective as the predicate devices. Thus, JAZZ Disposable Valve Kit is substantially equivalent to the listed predicate devices.