June 1, 2022

FUJIFILM medwork GmbH
% Dhara Buch
Regulatory Affairs Specialist
FUJIFILM Healthcare Americas Corporation
81 Hartwell Avenue, Suite 300
Lexington, MA 02421

Re: K221264
Trade/Device Name: FROG Forceps Valve (VAL1-F1-100)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: ODC
Dated: April 29, 2022
Received: May 2, 2022

Dear Dhara Buch:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221264

Device Name
FROG Forceps Valve VAL1-F1-100

Indications for Use *(Describe)*
The forceps valve is intended to facilitate passage of an endotherapy device, to prevent leak or back flow of air and/or fluids, and to enable the suction function of a FUJIFILM or Olympus 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.

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

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510(k) Summary

FUJIFILM medwork GmbH

FROG Forceps Valve (VAL1-F1-100)

Date: April 29, 2022

Submitter's Information:

FUJIFILM medwork GmbH
Medworkring 1
91315 Höchstadt, Germany

Contact Person:

Dhara Buch
Regulatory Affairs Specialist
Phone: 781-824-2708
E-Mail: dhara.buch@fujifilm.com

Identification of the Proposed Device:

Device Name:	FROG Forceps Valve (VAL1-F1-100)
Common Name:	Endoscope Channel Accessory
Product Code:	ODC
Device Class:	Class II
Classification:	Endoscope and accessories
Classification Number:	21 C.F.R. § 876.1500
Review Panel:	Gastroenterology/Urology

Predicate Device:

- JAZZ Forceps Valve (part of JAZZ Disposable Valve Kit) (K210625)

Intended Use / Indications for Use:

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

Device Description:

The FROG forceps valve forms a tight seal with the biopsy port to prevent leakage of biomaterial, provide easy passage of endotherapy devices, and support the suction function.

Comparison of Technological Characteristics:

A comparison of technological characteristics between the subject device and the predicate device is provided in the table below:

Device Details	Predicate Device	Subject Device
Device Name	JAZZ Forceps Valve (part of JAZZ Disposable Valve Kit)	FROG Forceps Valve (VAL1-F1-100)
510(k) number	K210625	To be assigned
Product code	ODC	ODC
Classification	II	II
Regulation Number	21CFR § 876.1500	21CFR § 876.1500
Manufacturer	FUJIFILM medwork GmbH	FUJIFILM medwork GmbH
Intended 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 forceps valve is intended to facilitate passage of an endotherapy device, to prevent leak or backflow of air and/or fluids, and to enable the suction function of a FUJIFILM or Olympus gastrointestinal endoscope.
Supplied Sterile	Yes, EO sterilized	No, used non-sterile
Single Use	Yes	Yes
Compatibility	FUJIFILM G7 Series	FUJIFILM G7 Series and Olympus GI Endoscopes
Environment of Use	Hospital and/or clinics	Hospital and/or clinics
Shelf life	3 years	2 years

Performance Data:

The proposed device was adopted into the biocompatibility testing of the predicate device 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 Standard ISO 10993-1, 'Biological evaluation of

medical devices - Part 1: Evaluation and testing within a risk management process,'" published September 4, 2020.

Bench testing was conducted to confirm the compatibility of the subject device with Olympus scopes.

Additional performance specifications were evaluated against pre-defined acceptance criteria to demonstrate the effectiveness of the device over its stated 2-year shelf life.

Bioburden testing was conducted according to USP 61.

Conclusions:

The subject device shares the same intended use and similar indications as the predicate device (K210625).

Bench testing demonstrates that the subject device is as safe and effective as the predicate device. Thus, subject device is substantially equivalent to the predicate device.