August 20, 2020

Fujifilm Corporation
% Kamila Sak
Regulatory Affairs Specialist
Fujifilm Medical Systems U.S.A, Inc.
81 Hartwell Avenue, Suite 300
Lexington, Massachusetts 02421

Re: K202130
Trade/Device Name: FUJIFILM Video Laparoscope, Model EL-R740M
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: July 30, 2020
Received: July 31, 2020

Dear Kamila Sak:

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,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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)*
K202130

Device Name
FUJIFILM Video Laparoscope Model EL-R740M

Indications for Use *(Describe)*
FUJIFILM Video Laparoscope EL-R740M is intended to be used with a video processor, light source, monitor, hand instruments, electrosurgical unit and other ancillary equipment for minimally invasive observation, diagnosis and treatment in general abdominal, gynecologic and thoracic areas.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K202130

510(k) SUMMARY
FUJIFILM Video Laparoscope EL-R740M

Date: August 19, 2020

Submitter's Information:

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

Contact Person:

Kamila Sak
Regulatory Affairs Specialist
Telephone: (347) 577-2309
E-Mail: kamila.sak@fujifilm.com

Identification of the Proposed Device:

Device Name:	FUJIFILM Video Laparoscope, Model EL-R740M
Common Name:	Laparoscope
Classification Number:	21 C.F.R. § 876.1500
Classification Name:	Endoscope and accessories
Regulatory Class:	Class II
Device Panel:	General & Plastic Surgery

Product Code Information:

Product Code Name	CFR Section	Product Code
Laparoscope, General & Plastic Surgery	21 CFR 876.1500	GCJ

Predicate Device:

- FUJIFILM Video Laparoscope EL-R740S (K192918)

Intended Use / Indications for Use:

FUJIFILM Video Laparoscope EL-R740M is intended to be used with a video processor, light source, monitor, hand instruments, electrosurgical unit and other ancillary equipment for minimally invasive observation, diagnosis and treatment in general abdominal, gynecologic and thoracic areas.

Device Description:

Video Laparoscope EL-R740M is comprised of a rigid insertion portion, cable portion, and scope connector. An optical system, CCD image sensor and electrical circuits are located within the distal end portion of the laparoscope. The video signal lines from the CCD sensor and the light guide fiber bundles are connected to the scope connector through the laparoscope.

Technological Characteristics:

The subject and predicate devices share the same mode of operation and intended use. The proposed Video Laparoscope Model EL-R740M differs from the predicate device in the following minor modifications:

- Dimensional and material changes to the insertion portion

Performance Data:

Photobiological safety of the subject device was performed in accordance with IEC 62471:2006.

Biocompatibility of the subject device was evaluated using the following consensus standards: ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2010, and ISO 10993-11:2017. 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 June 16, 2016.

Endoscope specific testing was conducted according to ISO 8600-1:2015.

Substantial Equivalence:

The subject device FUJIFILM Video Laparoscope EL-R740M is substantially equivalent to the predicate device FUJIFILM Video Laparoscope EL-R740S (K192918). The subject and predicate devices share the same intended use and indications. Bench testing demonstrates that the differences in technological characteristics and materials raise no new issues of safety or effectiveness. Thus, FUJIFILM Video Laparoscope EL-R740M is substantially equivalent to the predicate device.

Conclusions:

The subject device Video Laparoscope EL-R740M is substantially equivalent to the predicate device based on the same intended use, indications for use, and substantially equivalent technological characteristics and materials.