March 14, 2025

Olympus Medical Systems Corporation
℅ Rebecca Walker
Program Manager, Regulatory Affairs
Olympus Surgical Technologies of America
800 West Park Drive
Westborough, Massachusetts 01581

Re: K241842
Trade/Device Name: Luer-Split MAJ-2092
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: ODC
Dated: June 21, 2024
Received: June 26, 2024

Dear Rebecca Walker:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Mark J. Antonino -S

Mark J. Antonino, M.S.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology, and Urology 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: 07/31/2026
*See PRA Statement below.*

Submission Number *(if known)*

K241842

Device Name

Luer-Split MAJ-2092

Indications for Use *(Describe)*

The Luer-Split MAJ-2092 has been designed to be attached to the instrument channel port of Olympus endoscopes to allow both irrigation and the use of EndoTherapy accessories.

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.***

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# 510(k) Summary

Prepared on: 2025-02-14

## Contact Details

21 CFR 807.92(a)(1)

| | |
|---|---|
| Applicant Name | Olympus Medical Systems Corporation |
| Applicant Address | 2951 Ishikawa-cho Hachioji-shi Tokyo 192-8507 Japan |
| Applicant Contact Telephone | +81 42-642-269 |
| Applicant Contact | Mr. Shinichiro Kawachi |
| Applicant Contact Email | Shinichiro.Kawachi@Olympus.com |

## Device Name

21 CFR 807.92(a)(2)

| | |
|---|---|
| Device Trade Name | Luer-Split MAJ-2092 |
| Common Name | Endoscope and accessories |
| Classification Name | Endoscope Channel Accessory |
| Regulation Number | 876.1500 |
| Product Code(s) | ODC |

## Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

| Predicate # | Predicate Trade Name (Primary Predicate is listed first) | Product Code |
|---|---|---|
| K173105 | Side-Arm Adapter (G14732) | ODC |

## Device Description Summary

21 CFR 807.92(a)(4)

The Luer-Split MAJ-2092 ("Luer-Split") has been designed to be attached to the instrument channel port of endoscopes to allow both irrigation and the use of endoscopy accessories. The Luer-Split is a reusable device after appropriate cleaning and disinfection/ reprocessing as stated in the instruction manual accompanied with device. The Luer-Split is provided as a single model (MAJ-2092) and packed as a single unit.

The Luer-Split is mounted on the instrument channel port of endoscope and the sealing accessory (i.e., single use biopsy valve) is attached on the proximal end of the Luer-Split. The side arm/T-Pipe of the Luer-Split, also referred to as the irrigation port, is connected to the irrigation tube and irrigation equipment. EndoTherapy devices are inserted via attached sealing accessory to perform procedures.

## Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Luer-Split MAJ-2092 has been designed to be attached to the instrument channel port of Olympus endoscopes to allow both irrigation and the use of EndoTherapy accessories.

## Indications for Use Comparison

21 CFR 807.92(a)(5)

There are differences in the specific wording in the indications for use between the subject device and the predicate device; however, the fundamental intended use is the same. Both devices are intended to gain access to the working channel of endoscopes. The subject device is connected to a sealing accessory (biopsy valve) to resist backflow. This difference in wording does not describe a new disease, condition or patient population that the device is intended to treat, diagnose, prevent, cure or mitigate.

## Technological Comparison

21 CFR 807.92(a)(6)

The Luer-Split has similar technological characteristics and principles of operation as the predicate device. The subject device is a reusable, mutli-patient device, whereas the predicate is single use. The subject device is designed to connect to a biopsy valve to resist backflow, while the predicate device does not utilize a separate valve. Additionally, the subject device has the following differences in technological characteristics:

- Compatible instrument diameter range
- Shape of the arm on the adapter body

The differences above have been verified by completion of performance bench testing which demonstrate the technological differences do not raise any new issues of safety or effectiveness of the subject device.

## Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The following verification and validation testing activities were conducted after risk assessment evaluation in support of the substantial equivalence determination between the subject device and predicate device.

- Performance Testing – Bench
  - o Flow Rate
  - o Composite Durability
- Human Factors Validation
- Reprocessing Validation
- Biocompatibility Evaluation

Clinical testing is not applicable.

The verification and validation testing activities demonstrate that the technological differences between subject device and predicate device do not adversely affect device performance and the subject device is substantially equivalent to the predicate device.