April 15, 2020

MAQUET Cardiovascular, LLC
Mark Dinger
Sr. Regulatory Affairs Specialist
45 Barbour Pond Drive
Wayne, New Jersey 07470

Re: K191930
Trade/Device Name: 7 mm Extended Length Endoscope
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: March 12, 2020
Received: March 16, 2020

Dear Mark Dinger:

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)*

K191930

Device Name

7 mm Extended Length Endoscope

Indications for Use *(Describe)*

The 7 mm Extended Length Endoscope with Dissection Tip is indicated for visualization of a surgical cavity and dissection in endoscopic procedures and other minimally invasive surgical procedures allowing access for vessel harvesting, and is primarily indicated for patients undergoing endoscopic vessel harvesting for arterial bypass. It is indicated for patients requiring endoscopic tissue separation of the extraperitoneal or subcutaneous extremity and thoracic space. Extremity procedures include tissue dissection/vessel harvesting along the saphenous vein for use in coronary artery bypass grafting and peripheral artery bypass or radial artery for use in coronary artery bypass grafting. Thoracoscopic procedures include exposure and dissection of structures external to the parietal pleura, including nerves, blood vessels and other tissues of the chest wall.

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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7 mm Extended Length Endoscope Reprocessing Methods

510(k) Summary

Prepared in accordance with 21 CFR Part 807.92

510(k) Number: K191930

Date Prepared: 16 July 2019

Device Owner:
MAQUET Cardiovascular, LLC.
45 Barbour Pond Drive
Wayne NJ 07470
United States of America

Contact Personnel: Mark Dinger
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Email: mark.dinger@getinge.com
Phone: 973-709-7691 **Fax:** 973-909-9954

Trade Name: 7 mm Extended Length Endoscope

Device Generic Name: Endoscope and accessories

Classification:
Class II
GCJ; Endoscope and accessories, 21 CFR 876.1500

Predicate Device: (K014250) 7 mm Extended Length Endoscope (SE: 10 Jan 2002)

Device Description: The 7 mm Endoscope is a reusable product which consists of a stainless steel shaft housing optical and illumination components. The proximal end has an eyepiece for camera adapter attatchment, and a light post for light cable connection; the camera adapter and light cable are not included with the 7 mm Endoscope. The 7 mm Endoscope is supplied non-sterile, and must be cleaned and sterilized prior to each use.

Indications for Use: The 7 mm Extended Length Endoscope with Dissection Tip is indicated for visualization of a surgical cavity and dissection in endoscopic procedures and other minimally invasive surgical procedures allowing access for vessel harvesting, and is primarily indicated for patients undergoing endoscopic vessel harvesting for arterial bypass. It is indicated for patients requiring endoscopic tissue separation of the extraperitoneal or subcutaneous extremity and thoracic space. Extremity procedures include tissue dissection/vessel harvesting along the saphenous vein for use in coronary artery bypass grafting and peripheral artery bypass or radial artery for use in coronary artery bypass grafting. Thoracoscopic procedures include exposure and dissection of structures external to the parietal pleura, including nerves, blood vessels and other tissues of the chest wall.

Technological Characteristics

The Proposed 7 mm Extended Length Endoscope and the predicate devices have the following similarities:

- the same intended use,
- the same operating principles,
- incorporates the same basic design and materials,
- has same packaging.

The Proposed 7 mm Extended Length Endoscope and the predicate devices have the following differences:

- Added clarity to the Manual Cleaning method and added the following cleaning methods to provide more flexibility capability to the end user.
  - Manual Cleaning with Sonication
  - Automated Cleaning with Alkaline detergent
  - Automated Cleaning with Enzymatic detergent
  - Combined Automated Washing / Thermal High Level Disinfectant (in a washer/disinfecter).
- Expanded method in one modality and removed a method in another modality for sterilization.

The differences are not considered a technological difference and are substantially equivalent to the predicate device.

Safety and Performance:

MAQUET Cardiovascular, LLC., development process required that the following activities be completed during the development of the 7 mm Extended Length Endoscope:

- Performance Testing

The results of the in-vitro tests conducted demonstrate that the functionality and performance characteristics of the device are comparable to the previously cleared 7 mm Extended Length Endoscope.

Conclusion:

Based upon the information submitted in this Traditional 510(k) premarket notification, MAQUET Cardiovascular's 7 mm Extended Length Endoscope is substantially equivalent to the predicate device. The 7 mm Extended Length Endoscope is similar to the predicate devices in the intended use and the fundamental scientific technology of the device. The validation testing established that the 7 mm Extended Length Endoscope is substantially equivalent as the predicate device.