April 4, 2019

Olympus Surgical Technologies America
Mary Anne Patella
Senior Specialist, Regulatory Affairs
136 Turnpike Road
Southborough, MA 01772-2104

Re: K190164
Trade/Device Name: CleverLock Guidewire Locking Device and Biopsy Cap
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: ODC
Dated: January 30, 2019
Received: January 31, 2019

Dear Mary Anne Patella:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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)*

K190164

Device Name

CleverLock Guidewire Locking Device and Biopsy Cap

Indications for Use *(Describe)*

The locking device is an accessory used with endoscopic devices to lock the wire guide(s) in place during endoscopic procedures (e.g. ERCP). The integrated biopsy cap is designed to prevent reflux of body fluids.

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
CleverLock Guidewire Locking Device and Biopsy Cap

General Information

Contract Manufacturer:	PMC, LLC 1451 S. Miller Avenue Shelbyville, IN 46176 Phone: 317-421-2515
Establishment Registration Number:	3010408671
510(k) Submitter:	Olympus Surgical Technologies America Gyrus ACMI, Inc. 136 Turnpike Rd. Southborough, MA 01772-2104 Phone: 508-804-2600 Fax: 508-804-2624
Establishment Registration Number:	3003790304
Contact Person:	Mary Anne Patella Senior Specialist, Regulatory Affairs 508-804-2771 Maryanne.patella@olympus-osta.com
Date Prepared:	January 29, 2019

Device Description

Classification Name:	Endoscope and accessories
Regulation Number:	21 CFR 876.1500
Product Code:	ODC
Device Class:	Class II
Review Panel:	Gastroenterology/Urology
Trade Name:	CleverLock Guidewire Locking Device and Biopsy Cap
Generic/Common Name:	Locking device

Predicate Device

Wilson-Cook USW Cap and Wire Lock	K040137

Product Description

The CleverLock Guidewire Locking Device and Biopsy Cap is an accessory used with compatible endoscopic devices to lock the wire guide(s) in place during endoscopic procedures. The two components of the device are the guidewire locking device and the biopsy cap.

The skirt portion of the locking device is designed to attach to the biopsy port located on the endoscope barrel. The rigid skirt is matched to fit the scope handle to prevent its rotating during a wire engagement or disengagement. The lock arm has three (3) locking mechanisms (wire slots): inner slot, outer slot and lower slot to accommodate up to three (3) guidewires. The locking feature has a geometry which results in an "audible" click with tactile feedback when the wire has been fully engaged.

The biopsy cap is comprised of a cap seal and inner seal. The cap seal sits on top of the locking device skirt. The cap seal is designed with a self-closing slit to minimize fluid passage when all devices are removed from the biopsy channel. The inner seal attaches to the snap fit portion of the locking device; and is designed with a round opening to minimize fluid passage when there is a device inserted into the biopsy channel.

The CleverLock Locking Device and Biopsy Cap is available in one model only (MAJ-2455). The proposed CleverLock Locking Device and Biopsy Cap will be sold sterile and is intended for single patient use only.

Intended Use

The locking device is an accessory used with endoscopic devices to lock the wire guide(s) in place during endoscopic procedures (e.g. ERCP). The integrated biopsy cap is designed to prevent reflux of body fluids.

Technological Characteristics

The CleverLock has the same basic technological characteristics as the predicate Fusion Wire Guide Locking Device cleared under K040137. The subject and predicate device operate in the same manner to lock the wire guide(s) in place during endoscopic procedures. The indications for use of the CleverLock are the same as that of the predicate.

A detailed comparison of the CleverLock and its' predicate is provided in the following table.

Table 5.1 Comparison of Proposed and Predicate Device

	Proposed Device	**Predicate Device (K040137)**	
Device Name/ Characteristics	**CleverLock Guidewire and Biopsy Cap**	**Fusion Wire Guide Locking Device**	**Comments**
Indications for Use	The locking device is an accessory used with endoscopic devices to lock the wire guide(s) in place during endoscopic procedures (e.g. ERCP). The integrated biopsy cap is designed to prevent reflux of body fluids.	The Wilson-Cook USW Cap and Wire Lock Device is an accessory to be used with endoscopic biliary devices to lock the wire guide(s) in place during ERCP procedures.	Same as predicate
Device Function	Guidewire Locking Device with Biopsy Cap	Guidewire Locking Device with Cap	Same as predicate
Mechanics of Action	**Manual**	**Manual**	Same as predicate
Indirect Patient Contacting Materials	Main body: Polycarbonate Makrolon Rx2530	Plastic, unknown formulation	Similar to predicate; any differences confirmed through testing.
	Seal, Inside Rubber: Silicone KE-944-U	Rubber, unknown formulation	
	Seal Cover: Silicone KEG-2001-50-A/B		
Biocompatible	Yes	Unknown	Biocompatibility Tests passed
Sterilization	Gamma Radiation	Ethylene Oxide	Sterilization Validation passed
Single Use Only	Yes	Yes	Same as predicate
Attaches directly to the accessory port	Yes	Yes	Same as predicate
Double valve biopsy cap	Yes	Yes	Same as predicate
Wire Guide Diameter	.035”	.035”	Same as predicate
Secure guidewires of various sizes	.025” to .035” ET Guidewires .018” to .025” ERCP Guidewires	.025” or .018” guidewires	Same as predicate
Multiple locking positions	3	2	Similar to predicate

Summary of Non-Clinical Testing

Biocompatibility:
Biocompatibility testing on all patient contacting surfaces has been performed in compliance to relevant requirements of ISO-10993. Biocompatibility testing included the following tests:

- ISO 10993-5: 2009 Biological evaluation of medical devices – Part5: Tests for in vitro cytotoxicity

- ISO 10993-10: 2010 Biological evaluation of medical devices. Tests for irritation and sensitization
- ISO 10993-11: 2017 Biological evaluation of medical devices – Part 11: Tests for systemic toxicity
- United States Pharmacopeia 41, National Formulary 36, 2018. <151> Pyrogen Test

Sterilization:
The CleverLock will be delivered in a sterile state and is intended for single patient use only. Sterilization (gamma radiation) and packaging of the device was validated using the following standards:

- ANSI/AAMI/ISO 11607-1:2006 Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ANSI/AAMI/ISO 11137-2:2013 Sterilization of health-care products – Radiation – Part 2: Establishing the sterilization dose

Packaging integrity and performance testing on devices that had undergone accelerated aging support a labeled three-year shelf life.

Bench testing:

During design verification, the output of the design process was evaluated against the physical and performance specifications. The following performance tests were conducted:

- Scope Engagement Test
- Wire Locking Force Test
- Wire Retention and Lock Removal
- Insertion Force Test
- Leak Test
- Brush, Unlocking Test
- Angle Test
- Decay Test

Conclusion:
In summary, the CleverLock Guidewire Locking Device and Biopsy Cap is substantially equivalent to the predicate device and presents no new questions of safety or effectiveness.