January 27, 2020

STERIS Corporation
Jennifer Nalepka
Lead Regulatory Affairs Specialist
5960 Heisley Road
Mentor, OH 44060

Re: K191715
Trade/Device Name: Endoscope Tip Protector – Sterile
Endoscope Tip Protector – Non-sterile
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: OCU
Dated: January 9, 2020
Received: January 10, 2020

Dear Jennifer Nalepka:

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.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K191715

Device Name

Endoscope Tip Protector – Sterile, Endoscope Tip Protector – Non-sterile

Indications for Use *(Describe)*

The Endoscope Tip Protector is intended to be used on the distal tip of an endoscope for the purpose of protecting the endoscope's delicate lens and the endoscope's bending rubber during transport and storage. It may also be used on the distal tip of medical/surgical instruments to protect delicate components/mechanisms.

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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STERIS®

510(k) Summary
For
Endoscope Tip Protector – Sterile, Endoscope Tip Protector – Non-sterile

STERIS Corporation
5960 Heisley Road
Mentor, OH 44060

Contact: Jennifer Nalepka
Lead Regulatory Affairs Specialist
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Summary Date: July 30, 2019

STERIS Traditional 510(k) PREMARKET NOTIFICATION
Endoscope Tip Protector

1. Device Name

Trade Name:	Endoscope Tip Protector – Sterile, Endoscope Tip Protector – Non-sterile
Device Classification:	Class II
Common/usual Name:	Endoscopic Storage Cover
Classification Name:	Endoscope and accessories
Classification Number:	21 CFR 876.1500
Product Code:	OCU

2. Predicate Device

K951104 Endo-boot – endoscope tip protector

3. Description of Device

The Endoscope Tip Protector is a single-use molded protective cover to be used to protect endoscopes and medical/surgical instruments. The design of the Endoscope Tip Protector:

- Is composed on non-porous plastic material that allows for air flow
- Has minimal contact points with the endoscope or medical/surgical instruments
- Fits a wide variety of devices: 4.9mm -15mm outer diameter
- Protects the distal tip of the endoscope or medical/surgical instrument during transport or storage.

The Endoscope Tip Protector is available both non-sterile and sterile.

4. Intended Use

The Endoscope Tip Protector is intended to be used on the distal tip of an endoscope for the purpose of protecting the endoscope's delicate lens and the endoscope's bending rubber during transport and storage. It may also be used on the distal tip of medical/surgical instruments to protect delicate components/mechanisms.

5. Technological Characteristic Comparison Table

The Endoscope Tip Protector is very similar to the Endo-Boot in intended use. The differences between the proposed and predicate devices are the design and material of construction. The design is different in the predicate compared to proposed because the predicate has a sponge-like configuration whereas the proposed has an open cage-like configuration. These differences do not raise any new concerns of safety and effectiveness when compared to the predicate device.

Table 1 summarizes the difference between the proposed device and the predicate.

Table 1. Predicate Device Comparison Table

Feature	Endoscope Tip Protector (Proposed)	Endo-Boot – endoscope tip protector (Predicate K951104)	Comparison
Intended use	The Endoscope Tip Protector is intended to be used on the distal tip of an endoscope for the purpose of protecting the endoscope's delicate lens the endoscope's bending rubber during transport and storage. It may also be used on the distal tip of medical/surgical instruments to protect delicate components/mechanisms.	The Endo-Boot is used as a protective cover for the tip of the endoscope or other surgical instruments (i.e. rigid laparoscope, laparoscopic instruments) during storage and transport. The Endo-Boot will aid in protecting the lens and other delicate components from damage.	Similar
Length	10.2 cm	14 cm	Similar
Endoscope Compatible Outer diameter (OD)	4.9 mm – 15 mm	Small: 3.0 mm – 8.8 mm Large: 8.8 mm – 15.0 mm	The Endoscope Tip Protector is "one size fits all" and covers a wide variety of endoscope ODs within the range of the predicate device
Biocompatible	Yes	Not performed	The predicate Endo-boot – endoscope tip protector was not evaluated for biocompatibility because it initially was determined to be non-patient

Feature	Endoscope Tip Protector (Proposed)	Endo-Boot – endoscope tip protector (Predicate K951104)	Comparison
			contacting. The proposed Endoscope Tip Protector was determined to be indirectly patient contacting; therefore biocompatibility testing was performed.
Supplied Sterile	Yes, also supplied non-sterile	No	New sterile option for users.
Packaging	Sterile version: individually packaged in a Tyvek pouch, 15 per box Non-Sterile version: individually packaged in a poly bag, 50 per box	25 per dispenser box, 2 dispenser boxes per case	All Endoscope Tip Protectors are packaged individually.
Single Use	Yes	Yes	Identical
Disposable	Yes	Yes	Identical
Surface Contact with Endoscope	Minimal; internal diaphragm holds device in place	Along entire Endo-Boot	Bumps on diaphragm reduces surface contact with endoscope
Accessories	None	None	Identical

6. Description of Safety and Substantial Equivalence

Table 2 summarizes the verification activity that was performed with its respective acceptance criteria to ensure that this modification does not affect the safety or effectiveness of the endoscope or medical/surgical instrument.

Table 2. Summary of Verification Activities.

Testing	Acceptance Criteria	Proposed Endoscope Tip Protector
Attachment and Detachment Force	The Endoscope Tip Protector must be able to be attached and detached with minimal force	**PASS**
Scope Protection	The Endoscope Tip Protector must reduce the impact force to the endoscope compared to without protection	**PASS**
Transport Protection	The Endoscope Tip Protector must remain on the endoscope during transport	**PASS**
Longevity of Hold on Endoscope	The Endoscope Tip Protector must remain on the endoscope for at least 7 days	**PASS**
Irritation and Skin Sensitization	Must meet ISO 10993-10: 2010	**PASS**
Cytotoxicity	Must meet ISO 10993-5:2009	**PASS**
Sterility	The Endoscope Tip Protector must have a sterile version.	**PASS**
Packaging Validation	Sterile Packaging must meet ASTM F88/F88M-15, ASTM F2096-11, and ASTM F1886/F1886M-16	**PASS**

7. Conclusion

Based on the intended use, technological characteristics and non-clinical performance data, the subject device is as safe, as effective and performs at least as well as or better than the legally marketed predicate device (K951104), Class II (21 CFR 876.1500), product code OCU.