May 7, 2019

Meditech Endoscopy Ltd
% Thomas Schorre
Responsible Third-Party Official
Accelerated Device Approval Services, LLC
6800 S.W. 40th Street, Ste. 444
Ludlum, FL 33155-3708

Re: K191011
Trade/Device Name: Scope ProTech
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCU
Dated: April 15, 2019
Received: April 16, 2019

Dear Thomas Schorre:

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,

Shanil P. Haugen, Ph.D.
Acting Assistant Division 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)*
K191011

Device Name

Scope ProTech

Indications for Use *(Describe)*

The Scope ProTech is a single-use, sterile endoscopic tip protector that is intended to be used during the transport and storage of endoscopes for the protection of these delicate instruments. The Scope ProTech is intended for the protection of the distal tip and the bending rubber of endoscopes with a diameter of 2.7mm-8.0mm and 8.7mm-14.7mm. The Scope ProTech will aid in the protection of distal end, the lens and other delicate components from damage. It is not intended for use during sterilization.

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 – Summary of Safety and Effectiveness
Scope ProTech

510(k) number: K191011

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

Submitter's Identification:	Meditech Endoscopy Ltd
Address	Bowden House Luckyn Lane Basildon Essex SS14 3AX United Kingdom
Registered Establishment Number:	n/a
Owner/Operator Number:	n/a
Contact:	Peter Ramsey Managing Director
Telephone:	+44 1268 534035
Email:	peter@i-medical.net
Date of Summary:	29th March 2019
Device/Proprietary Name:	Scope ProTech
Common Name:	Endoscopic Storage Cover
Classification:	Endoscope and accessories.
Type of Submission	Traditional 510(k) – New Device
Product Code:	OCU
Product Class:	II
Regulation number:	21 CFR § 876.1500
Panel	Gastroenterology/Urology

Substantial Equivalence:			
Manufacturer	Trade Name	Regulation Number	510(k) Number
UNITED STATES ENDOSCOPY GROUP, INC	ENDOBOOT	876.1500	K951104

Description

The Scope ProTech is a single-use, sterile endoscopic tip protector which provides a simple, safe, and highly effective method of protecting the delicate optics of an endoscope, while allowing the tip to 'breath' and thus not allowing biofilm to form.

The Scope ProTech is available in two models to fit a range of scopes:

Product Code	Product Description	Size of scope
INOV8-028S	Scope ProTech Small	2.7 to 8mm
INOV8-028L	Scope ProTech Large	8.7 to 14.7mm

Table 1: Scope ProTech™ sizes

Indications for Use

The Scope ProTech is a single-use, sterile endoscopic tip protector that is intended to be used during the transport and storage of endoscopes for the protection of these delicate instruments. The Scope ProTech is intended for the protection of the distal tip and the bending rubber of endoscopes with a diameter of 2.7mm-8.0mm and 8.7mm-14.7mm. The Scope ProTech will aid in the protection of distal end, the lens and other delicate components from damage. It is not intended for use during sterilization.

Summary of the Determination of Substantial Equivalence & Performance Data

The subject device is substantially equivalent to the predicate, K951104, the Endo-Boot and a comparison of the key characteristics is summarised in Table 2.

Characteristic	Meditech Endoscopy Scope ProTech	US Endoscopy Endo-Boot (K951104)	Equivalence
Device Name	Scope ProTech	Endo-Boot™	n/a

MEDITECH ENDOSCOPY

Scope ProTech
Endoscopic Tip Protector

Ref: K191011

Characteristic	Meditech Endoscopy Scope ProTech	US Endoscopy Endo-Boot (K951104)	Equivalence
Indications for Use	The Scope ProTech is a single-use, sterile endoscopic tip protector that is intended to be used during the transport and storage of endoscopes for the protection of these delicate instruments. The Scope ProTech is intended for the protection of the distal tip and the bending rubber of endoscopes with a diameter of 2.7mm-8.0mm and 8.7mm-14.7mm. The Scope ProTech will aid in the protection of distal end, the lens and other delicate components from damage. It is not intended for use during sterilization.	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.	Substantially Equivalent
Intended User/Location	Healthcare professionals/ technicians and non-patient contacting Healthcare facility	Healthcare professionals/ technicians and non-patient contacting Healthcare facility	Equivalent
Storage and transport	The Scope ProTech is intended for use immediately after processing in an AER and is used during the storage and transport to and from the location of the procedure	The Endo-Boot™ is intended for use immediately after processing in an AER and is used during the storage and transport to and from the location of the procedure	Equivalent
Sterile	Yes, EtO sterilised	Non-sterile	Substantially Equivalent
Re-use	The Scope ProTech is a sterile single-use device and this is stated on the packaging	The Endo-Boot™ is a single use device and this is stated on the packaging	Equivalent
Scope Sizes	The Scope ProTech is supplied in two sizes intended to fit a range of scopes for each size (mm): Scope ProTech Small 2.7 - 8 Scope ProTech Large 8.8 - 14.7	The Endo-Boot™ is supplied in two sizes intended to fit a range of scopes for each size: Endo-Boot™ small 3.0 – 8.8 mm Endo-Boot™ large 8.8 – 15 mm	Substantially Equivalent

Characteristic	Meditech Endoscopy Scope ProTech	US Endoscopy Endo-Boot (K951104)	Equivalence
Materials	The Scope ProTech is manufactured using injection moulding using a soft polypropylene	The Endo-Boot™ is manufactured from a sponge	Substantially Equivalent
Instructions for use	Instructions for use included that includes graphical instructions, text and relevant warnings and cautions	Instructions for use included that includes graphical instructions, text and relevant warnings and cautions	Equivalent
Use on an endoscope	Slides over the distal tip of an endoscope	Slides over the distal tip of an endoscope	Equivalent
Distal tip protection	The Scope ProTech is intended to protect the entire distal end of the endoscope, covering the tip and delicate components	The Endo-Boot™ is intended to be used on the distal end however the placement of the device should ensure the distal tip of the endoscope is uncovered	Substantially Equivalent

Table 2: Comparison of characteristics between Scope ProTech™ and Endo-Boot™

Discussion

The Scope ProTech and the predicate both have equivalent intended use, the user, location of use, how they are used (slide onto the distal tip and during storage/ transport of endoscopes), the scope sizes covered and their non-re-use. Both devices include a set of instructions for use that includes graphical and text information with warnings/cautions. The indications for use are substantially equivalent as the intended use is equivalent however the clarification that the Scope ProTech is sterile, single-use and should not be used during sterilisation are important additions but do not impact the safety or effectiveness.

The main areas of difference are in the sterility aspect, with the Scope ProTech provided sterile to reduce bioburden and maintain cleanliness of the endoscope after reprocessing whereas the predicate is not provided sterile; the materials used with the Scope ProTech using an injection moulded soft polypropylene that provides impact protection whereas the predicate is manufacture from the thin sponge foam; the sizes of the scopes covered is lower for the Scope ProTech (2.75mm compared to 3mm) however the Endo-Boot™ can stretch further (max 15mm compared to 14.75mm) however both the subject and predicate device cover the range of endoscopes used in clinical practice and the size coverage is identified on the product and this does not impact safety or effectiveness; the distal tip protection with the open design of the Scope ProTech allowing for complete coverage of the distal tip (allowing it to aerate) whereas the predicate has to leave the distal tip uncovered; the clean/dirty identification as the Scope ProTech includes tabs that identify the status of the device and prevents re-use of a used device on a clean scope whereas the predicate does not have this identification.

These differences ensure the endoscope cleanliness is not affected by the use of a Scope ProTech, provide additional protection of the reprocessed scope over the distal tip and the delicate components, prevent re-use and therefore the Scope ProTech is at least as safe and effective as the predicate.

Non-Clinical Testing

The Scope ProTech has been tested for mechanical performance across the range of scope sizes and for sterility and shelf-life requirements. The Scope ProTech™ is provided individually packaged and is provided sterile (ethylene oxide). The device does not have any patient contacting parts and has an equivalent intended use to the predicate and are used in a similar way.

The following bench tests were performed on the device:

- Operating performance
- Scope compatibility and dimension
- Retention performance

The testing performed demonstrated that the proposed device and predicate device are equivalent.

Clinical Testing

No clinical data was used in the submission.

Summary

The Scope ProTech is accompanied by instructions for use which demonstrate how the device is used safely and the labelling and instructions for use have been compared with the predicate and found to be similar for their purpose.

The Scope ProTech has been compared to similar devices and the is substantially equivalent to the predicate for the parameters and the testing has demonstrated that the device does not introduce any additional risks when used in accordance with the instructions for use.

Conclusion

Based on the information presented in this submission, it is concluded that the Scope ProTech are equivalent to the Endo-Boot (K951104) with respect to intended use, design and technological characteristics.

The Scope ProTech is as safe and effective as the predicate devices for the protection of the delicate parts of the endoscope during transport and storage. There are no new indications for use, therefore by following the FDA 510(k) "Substantial Equivalence" decision making process, https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM284443.pdf, it is substantially equivalent to the predicate device.