April 20, 2018

Medtronic Xomed, Inc.
Shravan Chawla
Quality Engineer
6743 Southpoint Drive North
Jacksonville, FL 32216

Re: K173855
Trade/Device Name: Sharpsite™ AC Rigid Endoscope
Regulation Number: 21 CFR 874.4760
Regulation Name: Nasopharyngoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOB
Dated: March 20, 2018
Received: March 22, 2018

Dear Shravan Chawla:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 yours,

Eric A. Mann -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat 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)*
K173855

Device Name
Medtronic Sharpsite™ AC Rigid Endoscope and Sharpsite™ AC Endoscope Sterilization Tray

Indications for Use *(Describe)*
Sharpsite™ AC Rigid Endoscope: The Sharpsite™ AC Rigid Endoscopes are intended for use in surgical imaging in otolaryngology and Head and Neck procedures, including rhinology and endoscopic plastic and reconstructive surgery.

Sharpsite™ AC Sterilization Tray: Sharpsite™ AC Endoscope Sterilization Tray is intended to provide a specific configuration to hold, organize and protect Sharpsite™ AC Rigid Endoscope during their transport, storage and sterilization prior to use in surgical procedures.

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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510(k) Summary

This summary of safety and effectiveness is submitted in accordance with the requirements of 21 CFR 807.92.

I. Company

Address of Legal Manufacturer:	Medtronic Xomed, Inc. 6743 Southpoint Drive North Jacksonville, FL 32216 (904) 296-9600
Date:	18 December 2017
Contact Person:	Shravan Chawla Quality Engineer
Alternate Contact:	Gabriela Parana Sr Regulatory Affairs Manager

II. Device

Trade or Proprietary Name:	Sharpsite™ AC Rigid Endoscope
Common Name:	Sharpsite™ AC Rigid Endoscope
Class:	II
Product Code:	EOB
Classification Name:	21 CFR 874.4760 – Nasophayngoscope (flexible or rigid) and accessories

III. Description

The Sharpsite™ AC Endoscope Sterilization Tray has been designed to be used with Sharpsite™ AC Rigid Endoscopes for reprocessing. The Sharpsite™ AC Rigid Endoscope is the parent device and Sharpsite™ Tray is considered an accessory as the tray is specifically designed for the endoscopes. This Traditional 510(k) includes the following devices:

1. Sharpsite™ AC Rigid Endoscopes
2. Sharpsite™ AC Endoscope Sterilization Tray

Sharpsite™ AC Rigid Endoscopes

The Sharpsite™ AC endoscopes are rigid rod lens endoscopes for imaging and are available in diameters from 2.7 mm to 4.0 mm and in angles of view of 0, 30, 45 and 70 degrees. These endoscopes are reusable, autoclavable instruments and are provided non-sterile.

The Sharpsite™ Rigid Ear, Nose and Throat (ENT) endoscopes provide access and allow observation during otolaryngology and head and neck procedures. The device consists of rigid rod inserted into body orifice. The endoscope includes an optical system to visualize the image by direct view or with use of a camera. The endoscopes are provided non-sterile and can be reused by multiple methods as mentioned in the IFU. Each Sharpsite™ endoscope is fitted with a commercially available removable light port adapter for use with different manufacturers light cables. The Endoscrub sheath, removable light port adapter and light cables are not in the scope of this 510(k).

The Sharpsite™ AC Rigid Endoscopes are manufactured in multiple configurations that differ in insertion tube outer diameter and optical parameters. These endoscopes were previously cleared by FDA (K965233) for the visualization during otolaryngology and head and neck procedures.

Sharpsite™ AC Endoscope Sterilization Tray

Sharpsite™ AC Endoscopic sterilization tray is a container which is a reusable device that includes a base and lid. It is a single level thermoplastic instrument case designed to hold Sharpsite™ AC Rigid Endoscopes. The Sharpsite™ tray is specifically configured to organize, store, protect, transport and sterilize Sharpsite™ AC Rigid Endoscopes for use in surgical procedures.

IV. Indications for Use

The proposed 510(k) includes Sharpsite™ AC Rigid Endoscopes as the parent subject device. The submission also includes the Sharpsite™ Tray as an accessory. The indications for use for the parent device Sharpsite™ AC Rigid Endoscope are identical to the indications for use cleared in K965233. See below for the indications for use of the parent device and proposed indications for use of the tray.

Sharpsite™ AC Rigid Endoscopes (Parent Device)

The Sharpsite™ AC Rigid Endoscopes are intended for use in surgical imaging in otolaryngology and Head and Neck procedures, including rhinology and endoscopic plastic and reconstructive surgery.

Sharpsite™ AC Endoscope Sterilization Tray (Accessory)

Sharpsite™ AC Sterilization Tray is intended to provide a specific configuration to hold, organize and protect Sharpsite™ AC Rigid Endoscope during their transport, storage and sterilization prior to use in surgical procedures.

V. Predicate Device

Trade/Proprietary Name:	Sharpsite™ AC Rigid Endoscope
Classification Name:	Nasopharyngoscope (flexible or rigid) and accessories
Class/Panel:	Class II, EOB, 21 CFR 874.4760
510(k) Submitter/Holder:	Medtronic Xomed 6743 Southpoint Drive Jacksonville, FL 32216
510(k) Number:	K965233 (S.E. 04/04/1997)

VI. Comparison of Technological Characteristics

The subject and predicate device are based on the same technological characteristics:

1. Identical optical system diameter of the rigid rod
2. Same working length of the endoscope
3. Direction of view (DOV) is within the range of the predicate device
4. Field of View (FOV) is within the range of the predicate device
5. Same patient contacting materials are used in the predicate and subject device

The complete comparison of the technological characteristics between the subject and predicate device have been described in the table 5-1 below.

Table 5-1: Technological Characteristics of the Proposed Device and the Predicate Device

Attributes	Subject Device: Sharpsite™ AC Rigid Endoscopes	Predicate Device: Sharpsite™ AC Rigid Endoscopes (K965233)	Comparison
Light Transmission	Fiber optics	Fiber optics	Same
Light Source	External, connected via light guide to light guide connector	External, connected via light guide to light guide connector	Same
Image Transmission	Rigid Rod Lens	Rigid Rod Lens	Same
Direction of view (DOV)	0; 30; 45; 70 degrees	0; 30; 45; 70 degrees	Same
Field of View (FOV)	87; 97; 100; 102 degrees	87; 97; 100; 102 degrees	Same
Single Use/ Reusable	Reusable	Reusable	Same
Reprocessing	Cleaning, sterilization (steam, EtO, STERRAD)	Cleaning, sterilization (steam, EtO, STERRAD)	Same
Materials -insertion tube or shaft (outer surface) -insertion part (distal surface) -fiber optics -lens bonding	 Phynox Cobalt-Chromium-Nickel Alloy (CoCr20Ni15Mo) and 304 Stainless Steel (EN 10088 DIN 1.4301) Plane glass Glass fibers Epoxy resin (EPO TEK OG214)	 Phynox Cobalt-Chromium Nickel Alloy (CoCr20Ni15Mo) and 304 Stainless Steel (EN 10088 DIN 1.4301) Plane glass Glass fibers Epoxy resin (EPO TEK OG214)	Same
Packaging	Case with foam insert	Case with foam insert	Same
Accessories	Sterilization Tray	Not Included	Use of compatible Sharpsite™ AC Endoscope Sterilization Tray

Attributes	Subject Device: Sharpsite™ AC Rigid Endoscopes	Predicate Device: Sharpsite™ AC Rigid Endoscopes (K965233)	Comparison
			to sterilize and clean the endoscope per instructions in the IFU.

VII. Testing

Cleaning and Sterilization validations of the endoscopes in the Sterilization tray were completed to ensure the functionality after worst case cleaning and sterilization testing. Reprocessing and sterilization validation testing of the endoscope met all acceptance criteria and has demonstrated a sterility assurance level (SAL) of 10^{-6} for sterilization via steam, Ethylene Oxide (EO), STERRAD 100S and STERRAD NX sterilization. Biocompatibility assessment was also conducted to establish the safety and effectiveness of the endoscopes. Biocompatibility assessment included cytotoxicity, irritation and sensitization, and acute systemic toxicity in accordance with ISO 10993-1. Additional bench, animal or clinical testing was not required to establish substantial equivalence. All tests were successfully completed with passing results.

VIII. Conclusion

The indications for use, technology and performance characteristics of the subject Sharpsite™ AC Rigid Endoscope is substantially equivalent to the predicate Sharpsite™ AC Rigid Endoscope, cleared under K965233. The Sharpsite™ AC Rigid Endoscopes are as safe, as effective, and performs as well as the predicate devices.