June 14, 2019

Moss Tubes, Inc.
% Meghan McGovern
RA/QA Manager
Xeridiem Medical Devices
4700 South Overland Drive
Tucson, AZ 85714

Re: K190414
Trade/Device Name: Moss Gastrostomy Tube, Moss Nasal Tube - Mark IV
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: II
Product Code: PIF, KNT, BSS
Dated: May 14, 2019
Received: May 17, 2019

Dear Meghan McGovern:

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,

for
Shani 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K190414

Device Name
Moss Gastrostomy Tube

Indications for Use *(Describe)*
The Moss Gastrostomy Tube is used for gastric and proximal duodenal decompression plus duodenal feeding in adult populations.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
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Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K190414

Device Name
Moss Nasal Tube - Mark IV

Indications for Use *(Describe)*
The Moss Nasal Tube is used for decompression and simultaneous feeding in adult populations.

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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5.0 510(k) SUMMARY

5.1 General Information

Date Prepared:	14 May 2019
510(k) Applicant/Owner:	Moss Tubes, Inc 1929 Route 9 Castleton on Hudson, NY 12033
Applicant Contact:	Michael Moss Moss Tubes, Inc (518) 674-3109 mikemoss@nycap.rr.com
Correspondent:	Xeridiem Medical Devices (Contract Manufacturer) 4700 South Overland Drive Tucson, AZ 85714
Correspondent Contact:	Meghan McGovern Xeridiem Medical Devices (520) 882-7794 ext. 106 mmcgovern@xeridiem.com

5.2 Subject Device Information

5.2.1. Bundled Device #1 – Gastrostomy Tube

Trade Name:	Moss Gastrostomy Tube
Common Name:	Gastrostomy Tube
Classification Name:	Gastrointestinal tube and accessories (21 CFR 876.5980, Product Code PIF, KNT)
Classification Panel:	Gastroenterology/Urology
Classification:	Class II

5.2.2. Bundled Device #2 – Nasal Tube

Trade Name:	Moss Nasal Tube – Mark IV
Common Name:	Nasal Tube
Classification Name:	Gastrointestinal tube and accessories (21 CFR 876.5980, Product Code PIF, BSS)
Classification Panel:	Gastroenterology/Urology
Classification:	Class II

5.3 Legally Marketed Predicate Device Information (Unmodified)

5.3.1. Bundled Device #1 – Gastrostomy Tube

Trade Name:	Moss Gastrostomy Tube
Common Name:	Gastrostomy Tube
Classification Name:	Gastrointestinal tube and accessories (21 CFR 876.5980, Product Code KNT)
Classification Panel:	Gastroenterology/Urology
Classification:	Class II
510(k) Number:	K990389 (Held by Moss Tubes, Inc)

5.3.2. Bundled Device #2 – Nasal Tube

Trade Name:	Moss Nasal Tube – Mark IV
Common Name:	Nasal Tube
Classification Name:	Gastrointestinal tube and accessories (21 CFR 876.5980, Product Code BSS)
Classification Panel:	Gastroenterology/Urology
Classification:	Class II
510(k) Number:	K984629 (Held by Moss Tubes, Inc)

5.4 Reference Device

The proposed modification of the subject devices is to change the ENFit cap and connectors from ABS to Nylon. This same material change was recently reviewed by FDA under K171347, cleared 06 June 2017, for other ENFit enteral devices. Therefore, K171347 is considered a reference device for this submission.

Trade Name:	Bi-Funnel and Tri-Funnel Gastrostomy Feeding Tubes with ENFit connector
Common Name:	Gastrostomy Tube
Classification Name:	Gastrointestinal tube and accessories (21 CFR 876.5980, Product Code PIF)
Classification Panel:	Gastroenterology/Urology
Classification:	Class II
510(k) Number:	K171347 (Held by Xeridiem Medical Devices, contract manufacturer for subject devices)

5.5 Device Description

5.5.1. Bundled Device #1 – Gastrostomy Tube

The 18”, triple-lumen, 18FR Moss Gastrostomy Tube provides decompression while simultaneously feeding enterally. The suction channel supplements the

gastric site with aspiration within the proximal duodenum. Multiple holes in the suction lumen are designed to prevent mucosal occlusion. The second bore delivers an elemental diet three inches farther downstream into the distal duodenum, utilizing an industry standard ENFit connector. Refluxing excess is automatically removed while still within the proximal duodenum. The third lumen inflates a gastric retention balloon. Each device is individually packaged, and sterilized by Ethylene Oxide.

5.5.2. Bundled Device #2 – Nasal Tube

The 44", triple-lumen, 18FR Moss® Nasal Tube provides decompression while simultaneously feeding enterally. The suction channel supplements the aspiration within the distal esophagus and proximal duodenum. Multiple holes in the suction lumen prevent mucosal occlusion. The second bore delivers an elemental diet three inches farther downstream into the distal duodenum, utilizing an industry standard ENFit connector. Refluxing excess is automatically removed while still within the proximal duodenum. The third lumen inflates a gastric retention balloon at the esophagogastric junction. Each device is individually packaged, and sterilized by Ethylene Oxide.

5.6 Intended Use/Indications for Use

5.6.1. Bundled Device #1 – Gastrostomy Tube

The Moss Gastrostomy Tube is used for gastric and proximal duodenal decompression plus duodenal feeding in adult populations.

5.6.2. Bundled Device #2 – Nasal Tube

The Moss Nasal Tube is used for decompression and simultaneous feeding in adult populations.

5.7 Limited Device Modification

The subject device modifications are limited to changing the ENFit connector and cap material from ABS to Nylon. Otherwise, both subject devices remain unchanged from their legally marketed predicate devices.

5.8 Compliance with Design Controls

Substantial equivalence of each proposed device with their legally marketed predicates are by compliance to the required design control activities for the device modification. Required design controls activities were completed, including passing required design verification activities, such as ISO 80369-3 conformance to ENFit dimensions, chemical/mechanical stress test of ENFit Connectors/Caps, ENFit Connector-Funnel interface testing, biocompatibility,

sterilization, and shelf life. See Section 12 for a summary of design control activities.

5.9 Substantial Equivalence Conclusion

Based on successful completion of the required design control activities for the limited device modification that is the subject of this Bundled Special 510(k) premarket notification, it may be concluded that the proposed devices are substantially equivalent to their legally marketed predicates.

(End of Section)