January 6, 2021

Applied Medical Resources
Aeree Lee
Senior Manager, Regulatory Affairs
22872 Avenida Empresa
Rancho Santa Margarita, CA 92688

Re: K200021
Trade/Device Name: Applied Medical Anoscope
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FER
Dated: December 8, 2020
Received: December 9, 2020

Dear Aeree Lee:

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
Shanil P. Haugen, Ph.D.
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)*
K200021

Device Name
Applied Medical Anoscope

Indications for Use *(Describe)*
The Applied Medical Anoscope is intended for transanal use to provide physicians access to the anal sphincter, anus, and rectum and to perform various diagnostic and therapeutic procedures using additional accessories.

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

510(K) Submitter: Applied Medical Resources Corp.
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Rancho Santa Margarita, CA, 92688
(949) 713-8000

Contact Person: Aeree Lee
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Applied Medical Resources Corp.
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Date of Preparation: December 8, 2020

Trade Name: Applied Medical Anoscope

Common Name: Disposable anoscope

Classification: 21 CFR 876.1500, Endoscope & Accessories
Device Class: Class II
Product Code: FER, Anoscope and Accessories

Predicate Device: Sapimed Self Light Disposable Anoscope, K070913
Product Code: FER/GCP
The predicate device has not been subject to a design related recall.

Device Description: The Applied Medical Anoscope consists of a one-piece polycarbonate half round channel with a tapered closed tip. The device retracts the anal sphincter and provides access to the anorectal anatomy during transanal procedures.

Indications for use: The Applied Medical Anoscope is intended for transanal use to provide physicians access to the anal sphincter, anus, and rectum and to perform various diagnostic and therapeutic procedures using additional accessories.

Comparison of Technological Characteristics with the Predicate Device

The predicate and subject anoscopes are sterile, disposable access devices that are used to examine the anal sphincter, anus and rectum during anorectal procedures. Both devices have:

- A tapered tip for insertion
- A handle at the proximal end
- A full-length open channel for insertion of accessories
- Graduated markers on the circumference

The subject device differs from the predicate as follows:

- The predicate has a dedicated channel for application of a light source, while the subject device does not. However, the subject device has a 32mm lumen that is sufficiently large for direct visualization. Additionally, an external light source may be used to illuminate the working space.
- The predicate device has cm markings along the outside surface. The subject device has visual centimeter markings that are not labeled but that may be easily counted by the user.

Discussion of Performance Testing

Biocompatibility

Biocompatibility evaluation of the subject device was conducted in accordance with *ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process."* The subject device contacts tissue for less than 24 hours and the material was determined to be biocompatible when evaluated against the following endpoints:

- Cytotoxicity
- Intracutaneous Irritation
- Sensitization

Functional Performance

The anoscope is a simple one-piece device that provides a passage into the anal canal. There are no recognized performance standards for access devices of this kind. Therefore, Applied Medical devised criteria by which to assess safety and efficacy, including a computer-aided simulation and a compression test.

Conclusion

The Applied Medical Anoscope is substantially equivalent to the predicate Sapimed Disposable Anoscope in design and performance.