DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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May 17, 2016

Avantis Medical Systems, Inc.
Louis Fries
Consultant, Regulatory Affairs and Quality Assurance
2367 Bering Drive
San Jose, CA 95131

Re: K160356
Trade/Device Name: Third Eye Panoramic Auxiliary Endoscopy System - Resposable
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Codes: FDF, FDS
Dated: March 29, 2016
Received: April 4, 2016

Dear Louis Fries,

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160356

Device Name
Third Eye® Panoramic™ Auxiliary Endoscopy System – Resposable

Indications for Use *(Describe)*
The Avantis Medical Systems, Inc. Third Eye Panoramic Auxiliary Endoscopy System – Resposable is indicated for use as an accessory to a conventional colonoscope to provide additional visualization and illumination of the colon for diagnostic purposes.

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.

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510(k) SUMMARY

a) Applicant Information:

Date Summary Prepared	08 February 2016
Sponsor/Submitter	Avantis Medical Systems, Inc. 2367 Bering Drive San Jose, CA 95131
Correspondent Contact Information	Louis Fries Consultant, Regulatory Affairs & Quality Assurance Phone: 510-862-2034 Fax: 408-733-1847 E-mail: lfries@avantismedical.com

b) Device Information:

Device Common Name	Endoscope
Device Trade & Proprietary Name	Third Eye® Panoramic™ Auxiliary Endoscopy System - Resposable
Device Classification Name	Endoscope & Accessories (per 21 CFR 876.1500)
Device Classification Regulation	21 CFR 876.1500
Device Classification	Class II
Device Classification & Product Code	FDF, FDS

c) Identification of Predicate Device:

The Avantis Third Eye Panoramic Device - Resposable (TEPR) is substantially equivalent in operation and fundamental scientific technology to its previous version, the single-use Panoramic Device, cleared under K140595.

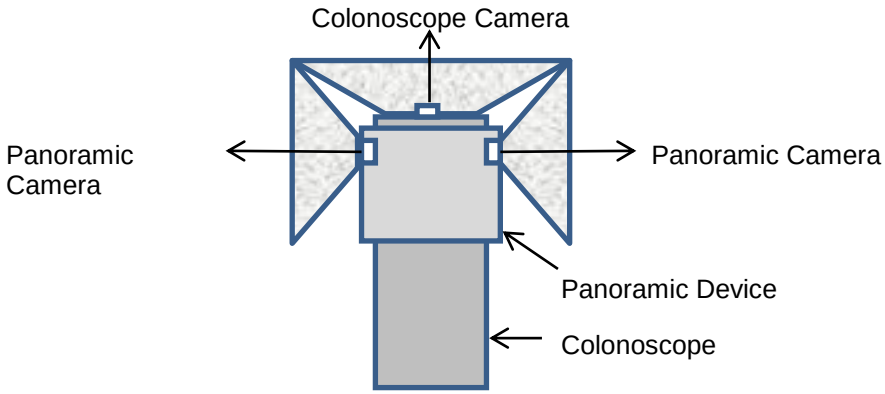
d) Device Description Summary:

The Third Eye Panoramic Auxiliary Endoscopy System - Resposable (consists of two main portions:

1. Resposable Panoramic Device (catheter with cameras and LED light sources at the distal end and connections to video processors at the proximal end) packaged and supplied as a non-sterile unit.
2. Facility Equipment: The non-disposable facility equipment portions of the device includes Third Eye Video Processors and cables (No change from predicate).

Description

The TEPR is designed as an adjunct device for use with a standard colonoscope to provide lateral and partial retrograde visualization and illumination of the colon during a colonoscopy procedure. Prior to insertion of a standard colonoscope, the TEPR is attached to the distal end of the colonoscope with a flexible clip. The TEPR travels with the colonoscope and provides continuous left-side and right-side views of the colon that supplement the forward view of the colonoscope. The images from the colonoscope (forward) and the Panoramic Device (left and right lateral) are displayed simultaneously on three separate monitors, providing a panoramic image with a total angle of view of approximately 310° as shown schematically below.



The TEPR utilizes the same video processors as used in the predicate.

e) Intended Use:

The Avantis Medical Systems, Inc. Third Eye Panoramic Auxiliary Endoscopy System - Resposable is indicated for use as an accessory to a conventional colonoscope to provide additional visualization and illumination of the colon for diagnostic purposes.

f) Substantial Equivalence:

The TEPR (the subject of this 510(k)) and the predicate single-use Third Eye Panoramic Auxiliary Endoscopy System (TEP) are both indicated for use with a colonoscope to provide visualization and illumination of the colon for diagnostic purposes using video camera(s).

The TEPR is indicated for the same use as the predicate device. Both utilize two cameras oriented laterally on the left and right sides of the device with angles of view that are sufficient to allow examination of the colonic mucosa in the lateral and backward directions.

Both the TEPR and predicate single-use TEP are inserted into the colon for viewing visualization and illumination and remain in place when the endoscopist is performing biopsies or polypectomies.

The TEPR contains the same cameras, and LED light sources as the predicate single-use TEP. It is constructed of the same materials as the predicate single-use TEP with the exception of the catheter shaft. The shaft of the TEPR is made of MT3000 heat-shrunk onto Pellethane (or Polytetrafluoroethylene (PTFE) as an equivalent alternate material) instead of Pebax used in the predicate device. The change was made to accommodate high-level disinfection.

The TEPR's left and right-lateral views, complementing the forward view of the colonoscope, may assist the endoscopist in determining the most appropriate direction to deflect the colonoscope's tip during intubation without excessive pressure against the wall of the colon, which may reduce patient discomfort and lower the risk of perforation of the colon.

The TEPR is substantially equivalent to the cleared predicate (single-use TEP) in fundamental design, materials of construction, manufacturing processes, and packaging.

The primary differences between the subject TEPR and the predicate single-use TEP are that the resposable TEPR is provided non-sterile, its shaft is made of MT3000 (or PTFE) instead of Pebax, and that it requires the user to perform a cleaning and disinfection procedure prior to first use and after each subsequent use.

All changes from the predicate device have been subjected to risk analysis and have been verified to meet current design specifications.

g) Scientific Technology

The TEPR includes the Panoramic Device containing two cameras and two LED light sources, and two Video Processors. Modifications made to the device, change of shaft material from Pebax to MT3000 (or PTFE), did not change the fundamental scientific technology of the device which is to provide additional visualization and illumination of the colon during colonoscopy. The testing described demonstrates that the proposed TEPR does not raise any new or unresolved issues for safety and efficacy.

h) Summary of Supporting Non-Clinical Performance Data

No animal testing was performed. Bench verification testing was conducted to verify that the modified device meets the design inputs and intended performance requirements. Results demonstrate that the TEPR performs as intended. The cleaning and disinfection procedures were validated to demonstrate effectiveness.