DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 14, 2016

Medivators, Inc.
Kristin Bergeson Padilla
Regulatory Affairs Associate
14605 28th Ave. North
Minneapolis, MN 55447

Re: K160846
Trade/Device Name: AmplifEYE
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FED
Dated: June 10, 2016
Received: June 13, 2016

Dear Kristin Bergeson Padilla:

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,

Joyce M. Whang -S

for

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)*
K160846

Device Name

AmpliEYE

Indications for Use *(Describe)*

To be attached to the distal end of the endoscope to facilitate endoscopic therapy, to be used for the following:

- Keeping the suitable depth of endoscope's view field
- Helping the endoscope with being inserted into the gastrointestinal tract

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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A Cantel Medical Company

Section 05 - 510(k) Summary

Manufacturer:	Medivators Inc., a Cantel Medical Company
Address:	3150 Pollok Drive Conroe, TX 77303 (800) 328-3345
Official Contact:	Kristin Bergeson Padilla Regulatory Affairs Associate, Medivators Inc.
Trade Name:	**AmplifEYE**
Common Name:	Endoscopic Access Overtube, Gastroenterology-Urology
Classification Name:	Endoscope and accessories
Product Code:	FED
Device Class:	II
Regulation No:	876.1500

Medivators Inc. has supplied the following information to the US Food and Drug Administration to support substantial equivalence of AmplifEYE to other endoscopic overtube visualization devices currently cleared for sale in the United States of America.

1. **Intended Use**
   AmplifEYE is intended to be used to facilitate endoscopic therapy by keeping the suitable depth of the endoscope's view field and by helping the endoscope with being inserted into the gastrointestinal tract.

2. **Device Description**
   The subject device is a sterile, single use, disposable medical device. It is designed to be placed on the distal end of an endoscope during endoscopic procedures to improve the physician's ability to visualize and examine the mucosa. AmplifEYE is made of injection molded polymer and consists of a main body tube with flexible wings arranged in a single row around one end of the main body tube. In a standard colonoscopy procedure, the endoscope is intubated through the rectum and advanced forward through the length of the colon. The endoscope is then retracted while the physician visually examines the colon mucosa for polyps or other abnormalities. The AmplifEYE wings fold down during intubation and movements that advance the endoscope forward so that forward movement is not hindered. During endoscope withdrawal, the wings open and fold outward to keep the depth of the endoscope's view field by manipulating the colonic folds and stabilizing the position of the endoscope within the intestinal lumen, thus aiding in the physician's ability to visualize and examine the mucosa.

3. **Comparison to Other Devices in Commercial Distribution Within the United States**
   AmplifEYE is equivalent in function, intended use and scientific technology to its predicate devices, Arc EndoCuff cleared under 510(k) K122565 and Arc Endocuff Vision cleared under 510(k) K151801.

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Similarities Between Subject and Predicate Devices

AmplifEYE and the predicate devices, Arc EndoCuff and Arc Endocuff Vision, have the same intended use, principle of operation and scientific technology. They are provided sterile and must be disposed of after a single use.

Differences Between Subject and Predicate Devices

The only notable differences between the subject device and the predicate devices are the method of sterilization and the open wings diameter. AmplifEYE is sterilized by ethylene oxide and the predicate devices, Arc EndoCuff and Arc Endocuff Vision, are sterilized by irradiation. The sterilization validation of AmplifEYE has demonstrated that the method of sterilization difference provides equivalent sterility assurance. AmplifEYE has an open wing diameter slightly greater than both of the predicate devices; however, bench testing and animal testing have demonstrated the open wing diameter difference results in equivalent performance and raises no questions of safety or efficacy.

A device comparison table which supports substantial equivalence of the subject device to the predicate device is provided below:

Table 1 – Device Comparison Table

Device Parameters	Subject Device – AmplifEYE	Predicate Device – Arc EndoCuff (K122565)	Predicate Device – Arc Endocuff Vision (K151801)
Trade Name	AmplifEYE	Arc EndoCuff AEC 110; AEC 120; AEC 140	Arc Endocuff Vision
Regulation Number	876.1500	876.1500	876.1500
Device Class	Class II	Class II	Class II
Certification Panel	Gastroenterology/Urology	Gastroenterology/Urology	Gastroenterology/Urology
Product Code	FED	FED	FED
Indications for Use	To be attached to the distal end of the endoscope to facilitate endoscopic therapy, to be used for the following: • Keeping the suitable depth of endoscope's view field • Helping the endoscope with being inserted into the gastrointestinal tract	To be attached to the distal end of the endoscope to facilitate endoscopic therapy, to be used for the following: • Keeping the suitable depth of endoscope's view field • Helping the endoscope with being inserted into the gastrointestinal tract	To be attached to the distal end of the endoscope to facilitate endoscopic therapy, to be used for the following: • Keeping the suitable depth of endoscope's view field • Helping the endoscope with being inserted into the gastrointestinal tract
Single Use	Yes	Yes	Yes
Supplied sterile	Yes	Yes	Yes
Method of Sterilization	Ethylene Oxide	Irradiation	Irradiation

Direct/Indirect Patient Contact	Yes	Yes	Yes
Material	Polymer conforming to ISO 10993-1 for biocompatibility	Polymers conforming to USP class VI	Polymers
Dimensions	Length: 0.97” Open wings diameter: 1.6” Folded wings diameter: 0.7”-0.74”	Length: 0.94” Open wings diameter: 1.27” Folded wings diameter: 0.63”-0.74”	Length: 0.98” Open wings diameter: 1.38” Folded wings diameter: 0.59”

4. Summary of Non-Clinical Performance Data

Medivators has conducted the following testing to demonstrate the safety and effectiveness of AmplifEYE:

- Design Verification
  - Force to Remove Testing
  - Force to Deflect Testing
- Animal Testing
- Shelf-life Validation
  - Functional Testing
  - Sterile Barrier Integrity Testing
- Sterilization Validation

5. Conclusion

AmplifEYE is substantially equivalent to predicate devices Arc EndoCuff cleared under 510(k) K122565 and Arc Endocuff Vision cleared under 510(k) K151801. Based on the intended use, technological characteristics, performance data and nonclinical tests performed, the subject device AmplifEYE is substantially equivalent to and as safe and as effective as the legally marketed predicate devices.