SEP 4 2012

510(k) Summary

Summary of Safety and Effectiveness

510(k) number K122565

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

Summary

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Date of Summary:	11th May 2012
Device Name:	EndoCuff
Proprietary Name:	Arc EndoCuff AEC 110; AEC 120; AEC 140
Classification:	Endoscope and/or accessories
Product Code:	FED
Product Class:	II
Code of Federal Regulation:	21 CFR 876.1500
Panel	Gastroenterology and Urology

Substantial Equivalence:			
Manufacturer	**Trade Name**	**Model**	**510(k) Number**
Olympus Optical Co. Ltd	Olympus Distal Attachment	MH & D-201 Series	K984358
Fujinon Corporation	Fujinon EC-450815 (BS-2 Balloon only)	BS-2 Balloon	K090116

Device Cross-Reference			
Arc EndoCuff	**MH-Series (K984358)**	**D-201 (K984358)**	**BS-2 Balloon (K090116)**
Model No. AEC 110	MH-463	D-201-13404	BS-2 Balloon
Model No. AEC 120	MH-466	D-201-14304	BS-2 Balloon
Model No. AEC 140	MH-466	D-201-15004	BS-2 Balloon

Description

Description of Device

The Arc EndoCuff has a short tube like shape with flexible hairs and is attached to the distal end of the endoscope to facilitate endoscopic therapy.

The Arc EndoCuff is designed to fit specific endoscopes (as designated on the packaging), and is supplied sterile following radiation sterilization and is single use only.

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

Summary of the Technological Characteristics of the Device compared to the Predicate Device

Design

The EndoCuff are a cylindrical shaped all polymer products. It utilises the combined properties of two polymer materials to self-retain to the designated endoscope(s). The product features a number of flexible "hair" features that fold within the structure of the product during intubation and forward movement when in use, and open out when drawn backward to control field of view.

Materials

EndoCuff raw materials have been purpose chosen as conforming to USP class VI and tested for biocompatibility (See Section 15).

Size:

The product is similar in bodily size and cylindrical shape to the products seen in both the Olympus Reusable (MH Series K984358) and Single-use (D-201 Series K984358) Distal Attachment model ranges.

The flexible hair features work at a similar diameter to the size of the 2nd predicate Fujinon BS-2 balloon (when inflated).

Summary of the Determination of Substantial Equivalence & Performance Data

The EndoCuff is used to maintain and maximise the endoscopes field of view during endoscopic therapy by manipulating colonic folds, maintaining a central position in the lumen and avoiding sudden slippage. The nominated predicate devices maximise the field of view in the same way, in particular:

- The Olympus Distal Attachment (MH Series and D-201 series K984358), is used to manipulate colonic folds; and
- The Fujinon BS-2 balloon (K090116) maintains central position in the lumen and avoids slippage by exerting circumferential pressure.

The bench testing demonstrates that the Endocuff design combines some of the benefits of both being a slim cylindrical device (like the Olympus product) and being able to stabilise and view the mucosa effectively on a greater diameter (as does the Fujinon balloon) but within the one product.

The design of the device is similar in length and is cylindrical in shape. Like both types of predicate devices, flexible polymers are the means for attachment/retention to the distal end of an endoscope.

The device contacts the patient in the same way and for the same period of time however they are made from different materials and are sterilised (where appropriate) using different methods.

The performance data showed that the sterilisation method selected (Arc EndoCuff is irradiated and the D-201 Series is Ethylene Oxide sterilised K984358) has not introduced any additional risks and the patient contacting materials have been tested for biocompatibility with reports demonstrating no negatives in safety or effectiveness

The bench testing has demonstrated that the device does not introduce any additional risks when undertaking endoscopic therapy and meeting the intended use.

Conclusion

After a review of the bench testing, it is concluded that the Arc EndoCuff is as safe and effective as the predicate devices for facilitating endoscopic therapy.

There are a few minor technological differences, in both materials used and the design. However the bio-compatibility testing shows that no additional risks are introduced from the materials used, and the performance testing demonstrates that there are no design weaknesses that could affect safety or effectiveness. There are no new indications for use and therefore by following the FDA 510(k) "Substantial Equivalence" decision making process,
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134783.htm

it is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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UNITED KINGDOM

SEP 4 2012

Re: K122565
Trade/Device Name: Arc EndoCuff AEC110; AEC120; AEC140
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FED
Dated: August 22, 2012
Received: August 22, 2012

Dear Mr. Champaneri:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) number K122565

Indications for Use

510(k) Number (if known): K122565

Device Name: Arc EndoCuff AEC110; AEC120; AEC140

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

Prescription Use **Yes** And/Or Over the Counter Use No

(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off) Concurrence of ~~CDRH, Office of~~ Device Evaluation (ODE)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K122565