DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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January 23, 2017

Boddingtons Plastics Ltd
Sarah Gibson
Regulatory Compliance Manager
Unit 6 Pattenden Lane, Marden
Tonbridge, Kent TN12 9QJ
United Kingdom

Re: K162205
Trade/Device Name: Arc EndoCuff and Arc Endocuff Vision
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FED
Dated (Date on orig SE ltr): November 10, 2016
Received (Date on orig SE ltr): November 14, 2016

Dear Sarah Gibson:

This letter corrects our substantially equivalent letter of December 9, 2016

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially (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 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" (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 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

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)*
K162205

Device Name

Arc EndoCuff and Arc Endocuff Vision

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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510(k) Summary

Summary of Safety and Effectiveness

510(k) number _K162205_____

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

Summary

Submitter's Identification:	Boddingtons Plastics Ltd Unit 6 Wheelbarrow Park Estate Pattenden Lane Tonbridge Kent TN12 9QJ United Kingdom
Contact:	Sarah Gibson
Telephone:	+44 1622 833700
Fax:	+44 1622 833701
Email:	Sarah.gibson@boddingtons.co.uk
Date of Summary:	01st August 2016
Device Name:	Arc EndoCuff and Arc Endocuff Vision
Proprietary Name:	Arc Endocuff Vision ARV110; ARV120; ARV130 and ARV140 Arc EndoCuff AEC110, AEC120, AEC130 and AEC140
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**
Boddingtons Plastics Limited	Arc EndoCuff	AEC110, AEC120, AEC130, AEC140	K122565
Boddingtons Plastics Limited	Arc Endocuff Vision	ARV110, ARV120, ARV130, ARV140	K151801

Description

Description of Device

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

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

The Arc EndoCuff and Arc Endocuff Vision are cylindrical shaped all polymer products. They utilise the combined properties of two polymer materials to self-retain to the designated endoscope(s). The products feature a number of flexible "hairs" 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.

Both the Arc EndoCuff and Arc Endocuff Vision devices are manually pushed onto the tip of the endoscope. It is designed to grip the endoscope sufficiently so as to prevent dislodgment during the procedure but without causing damage to the endoscope. At the end of the procedure, the device is removed either manually or with a purpose designed disposable tool before the endoscope is reprocessed.

The endoscope fitted with the Arc EndoCuff or Arc Endocuff Vision is inserted into the intestine either through the anus or a stoma and is used in the standard manner. The EndoCuff stabilizes the tip of the instrument in the bowel lumen enabling the shaft of the Arc endoscope to be more easily straightened on pulling back so avoiding excessive looping. This is because the cuff maintains the position of the tip without having to angle it acutely against the bowel wall to gain purchase. The device does not hinder forward motion or cause trauma.

During extubation, the device enables tip withdrawal in a more controlled fashion and provides improved visualisation by opening up the intestinal lumen for careful examination. Mucosal folds are everted and flattened enabling a more complete view of the areas of the bowel wall that were hidden behind mucosal folds.

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

Technological Characteristics

The purpose of this notification is to add additional marketing claims to the Arc EndoCuff and Arc Endocuff Vision, there are no new technological features incorporated in the devices.

Conclusion

It is concluded that the Arc EndoCuff and Arc Endocuff Vision remain safe and effective as the product design, materials and sterilisation methods remain unchanged from the original Premarket Notifications.

The expanded marketing claims are substantially equivalent and do not change fundamental scientific technology and intended use of the market cleared device. A Meta-Analysis of the Clinical literature supports the improvement of Adenoma Detection Rate claims.

Marketing Claims

The marketing claims were supported via non-clinical performance testing, clinical data, or were based on the device design, will be included within the advertising and promotional materials for Arc EndoCuff and Arc Endocuff Vision, and are as follows;

No.	Marketing Claims	Supporting Documentation
1	Arc EndoCuff assisted colonoscopy results in a statistically significant and clinically relevant improvement in adenoma detection rate in screening, surveillance, and diagnostic populations, as compared with unassisted colonoscopy.	Based on Clinical Data
2	Arc EndoCuff and Arc Endocuff Vision are designed to increase ADR by manipulating folds to maximize the viewable mucosa.	Based on Device Design In addition, based on Clinical Data
3	The Arc EndoCuff and Arc Endocuff Vision allows for controlled withdrawal.	Based on Device Design
4	The Arc EndoCuff and Arc Endocuff Vision have been designed to minimize the difficulties in loop reduction.	Based on Device Design
5	The Arc EndoCuff and Arc Endocuff Vision are designed with an outer diameter to provide increase wall apposition in the colon.	Based on Device Design

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No.	Marketing Claims	Supporting Documentation
6	The hinged arms of the Arc EndoCuff and Arc Endocuff Vision collapse into the body to minimize intubation force and insertion resistance.	Based on Device Design and In-vitro testing.
7	The internal ridges provide a tight grip on the distal end of the colonoscope and minimize risk of dislodgement.	Based on Device Design and Clinical Data.
8	The design is intended to minimize the risk of mucosal trauma.	Based on Device Design and In-vitro testing.
9	The Arc Endocuff Vision reduces the likelihood of red-out.	Based on Device Design