K082114
1 of 2

510(k) Summary

DEC 19 2008

General Information

Classification	Class II
Trade Name	Electrocautery Dilation Balloon
Submitter	Apollo Endosurgery, Inc. 7000 Bee Caves Road Suite 350 Austin, Texas 78746 Tel: (512) 328-9990
Contact	Dennis McWilliams President & CEO

Intended Use

The Electrocautery Dilation Balloon is intended for dilation of strictures of the esophagus and gastrointestinal tract and cutting, dissecting and cauterizing soft tissue during endoscopic electrosurgical procedures.

Predicate Devices

K993720	Cordis Maxi LD Dilation Balloon	Cordis
K023907	Cordis Maxi LD Dilation Balloon	Cordis
K073046	Endo Surgery Needle Knife	Ethicon

Device Description

The Electrocautery Dilation Balloon is indicated for dilation of strictures of the esophagus and gastrointestinal tract and cutting, dissecting and cauterizing soft tissue during endoscopic electrosurgical procedures. Using either endoscopic or fluoroscopic means, the balloon is placed at the physician selected site. Once in place, the clinician inflates the balloon to dilate the stricture.

The electrocautery needle knife may be used for cutting, dissecting and cauterizing soft tissue during endoscopic electrosurgical procedures. The needle knife is advanced and retracted with the proximal handle.

Materials

All materials used in the manufacture of the Electrocautery Dilation Balloon are suitable for this use and have been used in numerous previously cleared products.

Testing

Product testing was completed and met specification. Testing includes inflation/deflation/burst, atraumatic tip, electrocautery extension/retraction, and corrosion testing.

Summary of Substantial Equivalence

The Electrocautery Dilation Balloon is equivalent to the features of the predicate products. The indications for use, basic overall function, methods of manufacturing, and materials used are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 19 2008

Mr. Gregory Mathison
Vice President Regulatory Affairs
Apollo Endosurgery, Inc.
7000 Bee Caves Road, Suite 350
AUSTIN TX 78746

Re: K082114
Trade/Device Name: Electrocautery Dilation Balloon
Regulation Number: 21CFR §876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: II
Product Code: KNS
Dated: December 12, 2008
Received: December 17, 2008

Dear Mr. Mathison:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K082114
1 of 1

Indications for Use

510(k) Number (if known): K082114

Device Name: Electrocautery Dilation Balloon

Indications for Use: The Electrocautery Dilation Balloon is intended for dilation of strictures of the esophagus and gastrointestinal tract and cutting, dissecting and cauterizing soft tissue during endoscopic electrosurgical procedures.

Prescription Use ___X___ (Per 21 CFR 801.109) OR Over-The-Counter Use _____ (Optional Format 1-2-96)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082114