K080946

MAY 20 2008

Axcess Papillotome
510K Summary of Safety and Effectiveness
January 14, 2008

1. Sponsor Name

Sponsor/Manufacturer
ConMed Endoscopic Technologies
129 Concord Rd
Billerica, MA 01821
Telephone: 978 964 4251
Contact Individual: Beth Zis

2. Device Name

Proprietary Name: ConMed Axcess Papillotome
Common/Usual Name: Papillotome

3. Identification of Predicate or Legally Marketed Device

The Axcess Papillotome is substantially equivalent to the following devices:

- Bard Apollo Papillotome cleared under K982557
- Boston Scientific Corporation Autotome cleared under K013153

4. Device Description

The ConMed Axcess Papillotome is a multi-directional wire-guided tapered radiopaque tip catheter capable of accepting a .035" (.889 mm) guidewire. The Axcess Papillotome is a triple lumen device tapered from 7 to 4.5F over the distal 5mm. It has a 5mm tip and distal flexible section running from the proximal to the distal end of the cutting wire that allows multi-directional control of the device distal tip. The working length is 190cm.

5. Intended Use

The Axcess Papillotome is designed and recommended for transendoscopic cannulation and sphincterotomy of the Papilla of Vater and/or the Sphincter of Oddi.

6. Comparison of Technological Characteristics

The Axcess Papillotome and the predicates have similar design characteristics. They both have construction which consists of a handle, triple lumen shaft, a

cutting wire, and a precurved radiopaque tip. The device lengths and wire diameters are comparable. The materials of construction are different but the materials used are widely used in medical devices and tested to be biocompatible. The Axcess Papillotome is multidirectional whereas the Apollo Papillotome is not, however the BSC Autotome is a multidirectional Papillotome.

7. Performance Testing
The Axcess Papillotome meets electrical safety standards. In addition, in-vitro testing was conducted which demonstrated that the device meets its performance specifications.

8. Statement of Equivalency
The Axcess Papillotome is substantially equivalent in design, materials, construction and intended use as that of the predicate. The principal of operation of both devices are exactly the same. Since the Axcess Papillotome has the same intended use and technological characteristics as the predicate device, the Axcess Papillotome does not raise any new safety and efficacy concerns when compared to the similar legally marketed device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

MAY 20 2008

ConMed Endoscopic Technologies, Inc.
% Mr. Daniel W. Lehtonen
Intertek Testing Services NA, Inc.
2307 E. Aurora Road., Unit B7
TWINSBURG OH 44087

Re: K080946
Trade/Device Name: ConMed Axcess Papillotome
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: II
Product Code: KNS
Dated: May 2, 2008
Received: May 5, 2008

Dear Mr. Lehtonen:

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 (Premarket Approval), 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(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 Biometric's (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,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080946

Device Name: Axcess Papillotome

Indications For Use:

The Axcess Papillotome is designed and recommended for transendoscopic cannulation and sphincterotomy of the Papilla of Vater and/or the Sphincter of Oddi.

Prescription Use _X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(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 K080946