K051732

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SECTION 7

SUMMARY OF SAFETY AND EFFECTIVENESS

510(k) Summary of Safety and Effectiveness

Information supporting claims of substantial equivalence, as defined under the Federal Food, Drug and Cosmetic Act, respecting safety and effectiveness is summarized below. For the convenience of the Reviewer, this summary is formatted in accordance with the Agency's final rule "...510(k) Summaries and 510(k) Statements..." (21 CFR 807) and can be used to provide a substantial equivalence summary to anyone requesting it from the Agency.

NEW DEVICE NAME: Endoscopic Applicator

PREDICATE DEVICE NAME: Endoscopic Applicator

510(k) SUMMARY

Device Description

The Endoscopic Applicator device is a sterile single use, disposable device intended for use in delivering hemostatic agents to bleeding surgical sites through a 5mm trocar or larger. The Endoscopic Applicator consists of two components; (1) a minimally reflective stainless steel cannula and (2) a plastic stylet (obturator). The Endoscopic Applicator is designed with a luer connector, for connection to a syringe containing the hemostatic agent.

The packaging used for the Endoscopic Applicator is a pouch that consists of a see-through laminated film and TYVEK. Alternatively, a second pouch may be used. Either package configuration is placed within a paperboard carton.

Intended Use

The Endoscopic Applicator is intended for use in delivering hemostatic agents to bleeding surgical sites through a 5mm trocar or larger.

Continued on next page

SUMMARY OF SAFETY AND EFFECTIVENESS, Continued

Indications Statement	The Endocopic Applicator is indicated for use in delivering hemostatic agents to bleeding surgical sites through a 5mm trocar or larger.
Technological Characteristics	The technological characteristics of the new device are the same as the predicate device in that they both consist of a cannula and a stylet that is used to deliver hemostatic agents to bleeding sites through a 5mm trocar or larger. The new device is provided sterile, for single patient use and is disposable.
Performance Data	The Endoscopic Applicator(New Device) and the predicate device have the same intended use. The new device is substantially equivalent to the predicate device in intended use, technological characteristics, design, components and materials, therefore, performance testing was considered unnecessary. Clinical data was deemed unnecessary to demonstrate equivalence of the new device to the predicate device for its intended purpose.
Conclusions	Based on the 510(k) summaries and 510(k) statements (21 CFR 807) and the information provided herein, we conclude that the new device is substantially equivalent to the Predicate Device under the Federal Food, Drug, and Cosmetic Act.
Contact	Peter M. Cecchini Fellow, Regulatory Affairs ETHICON, Inc. Rt. #22, West Somerville, NJ 08876-0151
Date	June 27, 2005

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 9 - 2005

Mr. Peter M. Cecchini
Fellow, Regulatory Affairs
ETHICON, Inc.
Route 22 West
Somerville, New Jersey 08876

Re: K051732
Trade/Device Name: Endoscopic Applicator
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: June 27, 2005
Received: June 28, 2005

Dear Mr. Cecchini:

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 (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Barbara Buchholz for

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K051732

INDICATION FOR USE

510(k) Number (if known):

Device Name: Endoscopic Applicator

Indications for Use: The Endoscopic Applicator is intended for use in delivering hemostatic agents to bleeding surgical sites through a 5mm trocar or larger.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-9G)

Barbara Buchman for MKM

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K051732