

510(k) Summary of Safety and Effectiveness

K980815 PG. 1 of 2

MAY 1 1998
Statement

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.

Device
description

All device functions, scientific concepts, significant physical and performance characteristics (i.e. device design, materials, physical properties, etc.) are identical to the design and manufacture described in 510(k) #970720.

Intended use

The ENDOPATH® EZ45 Endoscopic Linear Cutter is intended for transection, resection, and /or the creation of anastomoses.

Indications
statement

The ENDOPATH® EZ45 Endoscopic Linear Cutter is intended for transection, resection, and /or creation of anastomoses, has application in multiple open or minimally invasive surgical procedures, including radical prostatectomy, and can be used with staple line or tissue buttressing materials, such as bovine pericardium.

Technological
characteristics

The technological characteristics of the ENDOPATH® EZ45 Endoscopic Linear Cutter are identical to those described in 510(k) #970720.

Performance
data

The ENDOPATH® EZ45 Endoscopic Linear Cutter performance is identical to that described in 510(k) #970720.

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510(k) Summary of Safety and Effectiveness, continued

Conclusion Based on the 510(k) summaries and 510(k) statements (21 CFR §807) and the information provided herein, we conclude that the ENDOPATH® EZ45 Endoscopic Linear Cutter is substantially equivalent to the Predicate Device under the Federal Food, Drug and Cosmetic Act.

Contact Edwin O. Billips, RAC
Senior Associate
Regulatory Affairs Department
Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, Ohio 45242

Date April 29, 1998



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 1998

Ms. Lorri Chavez
Project Manager, Regulatory Affairs
Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, OH 45242-2839

Re: K980815
Endopath® EZ45 Endoscopic Linear Cutter
Dated: March 2, 1998
Received: March 3, 1998
Regulatory Class: II
21 §CFR 876.1500/Procode: 78 KOG

Dear Ms. Chavez:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

K980815

Statement

Following is the Indications for Use Statement:

510(k) Number: K980815

Device Name: ENDOPATH® EZ45 Endoscopic Linear Cutter

Indications for Use:

The ENDOPATH® EZ45 Endoscopic Linear Cutter is intended for transection, resection, and /or creation of anastomoses, has application in multiple open or minimally invasive surgical procedures, including radical prostatectomy, and can be used with staple line or tissue buttressing materials, such as bovine pericardium.

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Robert P. Sattler
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number: K980815

Prescription Use
(Per 21 CFR 801.109)

Over-the-Counter Use