JUN 27 1997

Appendix A: 510(k) Summary of Safety and Effectiveness

K970720

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

The ENDOPATH® EZ45 Endoscopic Linear Cutter is a sterile, single patient use instrument that delivers two, double-staggered rows of staples while simultaneously dividing the tissue between rows. [The ENDOPATH® EZ45 No Knife Endoscopic Linear Stapler is a sterile, single patient use instrument that delivers two, double-staggered rows of staples.]

The instrument is designed for use in procedures that do not require insufflation. The instruments' safety lock-out feature is designed to prevent firing an unloaded instrument or prevent a used reload from being refired. The instruments have a staple line that is approximately 45 mm long and a cut line [linear cutter only] that is approximately 41 mm long. A staple retaining cap on the reload protects the staple leg points during shipping and transportation.

The instrument is reloadable with a thin (vascular), white reload; a standard, blue reload; or a thick tissue, green reload. Do not reload the instrument more than seven times for a maximum of eight firings per instrument. The use of the instrument with staple line buttressing materials may reduce the number of firings.

Intended use

For transection, resection, [and/or the creation of anastomoses].

Indications statement

The ENDOPATH® EZ45 Endoscopic Linear Cutter [and the ENDOPATH® EZ45 No Knife Endoscopic Linear Stapler] has application in multiple open and other minimally invasive surgical procedures for transection, resection, [and/or creation of anastomoses] and can be used with staple line or tissue buttressing materials, such as bovine pericardium.

Continued on next page

Appendix A: 510(k) Summary of Safety and Effectiveness, Continued

Technological characteristics	The technological characteristics of the New Devices are the same as the Predicate Device.
Performance data	Pre-clinical laboratory evaluations were performed to ensure that the devices can be used as designed. The studies demonstrated acceptable performance in transecting, resecting, and/or creation of anastomoses and for use with buttressing materials.
Conclusion	**Based on the 510(k) summaries and 510(k) statements (21 CFR §807) and the information provided herein, we conclude that the New Devices are substantially equivalent to the Predicate Device under the Federal Food, Drug and Cosmetic Act.**
Contact	Lorri Chavez Ethicon Endo-Surgery, Inc. 4545 Creek Road Cincinnati, Ohio 45242
Date	February 25, 1997

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

JUN 27 1997

Re: K970720
Trade Name: ENDOPATH® EZ45 Endoscopic Linear Cutter and ENDOPATH® EZ45 No Knife Endoscopic Linear Stapler
Regulatory Class: II
Product Code: KOG
Dated: May 21, 1997
Received: June 10, 1997

Dear Ms. Chavez:

We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are 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 devices, 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 devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your devices 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 devices in the Federal Register. Please note: this response to your premarket notification submissions 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 devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices 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) 594-4595. Additionally, for questions on the promotion and advertising of your devices, 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/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Appendix B: Indications for Use Statement

Statement

Indications for Use Statement:

510(k) Number: K 970720

Device Names: The ENDOPATH® EZ45 Endoscopic Linear Cutter and the ENDOPATH® EZ45 No Knife Endoscopic Linear Stapler.

Indications for Use: The ENDOPATH® EZ45 Endoscopic Linear Cutter [and the ENDOPATH® EZ45 No Knife Endoscopic Linear Stapler] has application in multiple open and other minimally invasive surgical procedures for transection, resection, [and/or creation of anastomoses] and can be used with staple line or tissue buttressing materials, such as bovine pericardium.

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K970720

Prescription Use ✓
(Per 21 CFR 801.109)