AUG 1 2001

PROTECTIV* ACUVANCE IV Catheter System
510(k) Summary of Safety and Effectiveness

Company
Ethicon Endo-Surgery, Inc.
4545 Creek Rd.
Cincinnati, OH 45242

Contact
Katie Fordyce
Regulatory Affairs Associate

Date Prepared:
July 6, 2001

Name of Device
Trade Name: PROTECTIV* ACUVANCE IV Catheter System
Classification Name: Catheter, Intravascular (short-term)

Predicate Devices: PROTECTIV* ACUVANCE IV Catheter System

Device Description: Intravascular catheters are single use devices which provide access to veins or arteries.

Intended Use: A properly placed I.V. catheter provides access to a vein or artery. The I.V. Catheter System is designed for single use and has a needlestick protection feature. The risk of accidental needlesticks is reduced by a self-blunting needle system activated automatically as the catheter is threaded into the vessel. These catheters may be used for any patient population with consideration given to patient size, appropriateness for the solution being infused, and duration of therapy. 14 to 22 gauge catheters may be used with power injectors up to 300 psi.

Technological Characteristics: The technological characteristics of the new device are the same as those of the predicate device. No changes (materials, specifications, manufacturing or sterilization processes) have been made to the currently marketed catheters. The catheters differ from the currently marketed catheters only in the instructions for use which now include use of the 14 to 22 gauge catheters with power injectors up to 300 psi. The use with power injectors claim is the same as the claim on other Ethicon Endo-Surgery (previously Johnson & Johnson Medical) catheters with regard to use with power injectors.

Performance Data: Bench testing demonstrates that the 14 to 22 gauge ACUVANCE catheters are appropriate for use with power injectors up to 300 psi.

*Trademark

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 2001

Ms. Katie Fordyce
Regulatory Affairs Associate
Ethicon Endo-Surgery, Incorporated
4545 Creek Road
Cincinnati, Ohio 45242-2839

Re: K012128
Trade/Device Name: PROTECTIV ACUVANCE IV Catheter System
Regulation Number: 880.5200
Regulatory Class: II
Product Code: FOZ
Dated: July 6, 2001
Received: July 9, 2001

Dear Ms. Fordyce:

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 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). 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) 594-4692. 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" (21CFR 807.97). Other general information on ycur 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,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K012128

Device Name: PROTECTIV* ACUVANCE IV Catheter System

Indications for Use:

A properly placed I.V. catheter provides access to a vein or artery. The I.V. Catheter System is designed for single use and has a needlestick protection feature. The risk of accidental needlesticks is reduced by a self-blunting needle system activated automatically as the catheter is threaded into the vessel. These catheters may be used for any patient population with consideration given to patient size, appropriateness for the solution being infused, and duration of therapy. 14 to 22 gauge catheters may be used with power injectors up to 300 psi.

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

Concurence of CDRH, Office of Device Evaulation (ODE)

(Optional Format 3-10-98)

Patricia Cusenza

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K012128