K030571

ACUVANCE® PLUS Safety IV Catheter, PROTECTIV PLUS® Safety IV Catheter, OPTIVA® IV Catheter 510(k) Summary of Safety and Effectiveness

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

MAR 2 6 2003

Contact
Katie Fordyce
Regulatory Affairs Associate II

Date Prepared:
February 21, 2003

Name of Device
Trade Name: ACUVANCE PLUS Safety IV Catheter, PROTECTIV PLUS Safety IV Catheter, OPTIVA IV Catheter
Classification Name: Catheter, Intravascular (short-term)

Predicate Devices: ACUVANCE PLUS Safety IV Catheter, PROTECTIV PLUS Safety IV Catheter, OPTIVA IV Catheter

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

Indications for Use:

ACUVANCE PLUS Safety IV Catheter: 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.

PROTECTIV PLUS Safety IV Catheter: The PROTECTIV PLUS I.V. Catheter is designed for single use. A properly placed I.V. catheter provides access to a vein or artery. The PROTECTIV PLUS Safety I.V. Catheter is designed to minimize inadvertent needlesticks. During catheter insertion, a needle guard can be locked over the introducer needle. 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. 16G to 24G catheters may be used with power injectors up to 300 psi.

OPTIVA IV Catheter: The OPTIVA I.V. Catheter is designed for single use. A properly placed I.V. catheter provides access to a vein or artery. 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. 16G to 24G catheters may be used with power injectors up to 300 psi.

Technological Characteristics: The catheter tube material has been modified for the IV Catheters. This new material is a different formulation of the material in the predicate devices. All other technological characteristics of the new device remain the same as those of the predicate device.

Performance Data: Bench testing and biocompatibility data demonstrate that the new material is equivalent to the current material.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 8 2003

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

Re: K030571
Trade/Device Name: ACUVANCE PLUS Safety IV Catheter, PROTECTIV PLUS Safety IV Catheter, OPTIVA IV Catheter
Regulation Number: 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: February 21, 2003
Received: February 24, 2003

Dear Ms. Fordyce:

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 (301) 594-4618. 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,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K030571

Device Name: ACUVANCE PLUS Safety IV Catheter, PROTECTIV PLUS Safety IV Catheter, OPTIVA IV Catheter

Indications for Use:

ACUVANCE PLUS Safety IV Catheter:

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 injector up to 300 psi.

PROTECTIV PLUS Safety IV Catheter

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OPTIVA IV Catheter:

The OPTIVA I.V. Catheter is designed for single use. A properly placed I.V. catheter provides access to a vein or artery. 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. 16G to 24G catheters may be used with power injectors up to 300 psi.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Rebecca Cucente

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K030571

(Optional Format 3-10-98)