K073471

APR 30 2008

ADVANTAGE MEDICAL DEVICES

TODAY'S INNOVATION FOR TOMORROW'S HEALTHCARE ADVANTAGE

510(k) SUMMARY

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Date Prepared: November 26, 2007

Device Trade Name: VantageCath™

Device Common Name: Intravascular Catheter

Classification Name: Catheter, Intravascular, Therapeutic, Short-Term Less Than 30 days

Device Class: II

Procode: FOZ

CFR Reference: 880.5200

Predicate Device: BD Nexiva™ Closed IV Catheter System
BD Insyte™ Autoguard Intravascular Catheter

Predicate 510(k) #: K032843 (BD Nexiva)/K971339 (BD Insyte Autoguard)

Device Description: The VantageCath™ is a short-term intravascular catheter that includes a needle-shielding feature. After threading the catheter into the vein, the sharps safety feature is activated and the needle is retracted into the cylindrical needle shield. The catheter hub and needle assembly components are automatically separated.

It is manufactured with conventional medical grade, biocompatible materials. It operates as a safety device by providing a sharps safety feature, thus minimizing the opportunity for accidental needle sticks.

It is supplied sterile for single use only.

Intended Use:

The VantageCath™ is an intravascular catheter that allows the health care practitioner to sample blood and administer fluids or medication intravenously. These catheters may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness for the solution being infused, and the duration of therapy.

The VantageCath™ catheter provides a shielding mechanism intended to reduce the incidence of accidental needle sticks. When the needle retracts into the needle-shielding barrel, the catheter hub and needle assembly components are automatically separated.

Technology Comparison:

The VantageCath™ is substantially equivalent to the predicate devices. The new device and predicate devices are similar in function, composition, and intended use.

Nonclinical Testing:

Standard biocompatibility tests were performed on the VantageCath™ to establish device safety. The tests and assays performed are typically performed for these medical devices. All tests were performed in accordance with US FDA General Program Memorandum #G95-1 and Part-10993-1 of the International Standard Organization (ISO) Standard (Biological Evaluation of Medical Devices) by Edwards Lifesciences LLC Quality Laboratory. The studies indicate that the VantageCath™ is biocompatible and safe for its intended use.

Conclusion of Comparison:

The VantageCath™ is substantially equivalent to the currently-marketed predicate devices.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Advantage Medical Devices
C/O Mr. Casey Conry
Responsible Third Party Official
Underwriters Laboratories, Incorporated
1285 Walt Whitman Road
Melville, New York 11747

APR 30 2008

Re: K073471
Trade/Device Name: VantageCath™
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: April 15, 2008
Received: April 17, 2008

Dear Mr. Conry:

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/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ADVANTAGE MEDICAL DEVICES
TODAY'S INNOVATION FOR TOMORROW'S HEALTHCARE ADVANTAGE

INDICATIONS FOR USE

510(k) Number (if known):_____

Device Name: VantageCath™

Indications for Use:

The VantageCath™ is a short-term intravascular catheter which allows health care practitioner to sample blood and administer fluids or medication intravenously. These catheters may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness for the solution being infused, and the duration of therapy.

The VantageCath™ catheter provides a shielding mechanism intended to reduce the incidence of accidental needle sticks. When the needle retracts into the needle-shielding barrel, the catheter hub and needle assembly components are automatically separated.

Prescription Use X Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) AND/OR (21 CFR 807 Subpart C)

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

~~Concurrence~~ of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K073471

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