K113565

510(k) Summary

MAY 18 2012

Submitter: Edwards Lifesciences LLC
One Edwards Way
Irvine, CA 92614-5686

Contact Person: Marguerite Thomlinson, JD, BSME
Director of Regulatory Affairs
Phone: (949) 756-4386
Fax: (949) 809-5676

Date Prepared: November 30, 2011

Trade Name: Multi-Med Central Venous Catheters
Vantex Central Venous Catheters

Classification Name: Intravascular Catheter (21 CFR Part 880.5200)

Product Class/ Product Code: Class II/FOZ

Predicate Devices: K955839: Multi-Med Multi-Lumen CVCs
K992532: Vantex CVCs with Oligon Material
K091709: Multi-Med CVCs and Vantex CVCs
K100739: VolumeView System
K110167: PreSep Oligon Oximetry Catheters

Device Description: The Multi-Med Central Venous Catheters (Multi-Med CVCs) and Vantex Central Venous Catheters (Vantex CVCs) and their respective convenience kits are used with Edwards monitoring instruments. They are used in patients who require the administration of solutions, blood sampling, central venous monitoring and injection of contrast media. The Multi-Med CVCs and Vantex CVCs can be used with an uncoated stainless steel guidewire (SS guidewire) or a PTFE-coated Nitinol core guidewire (Nitinol guidewire). The guidewire is included with the Multi-Med CVCs and Vantex CVCs in convenience kits or the guidewire can be packaged as a separate component.

Indications for Use:	The Multi-Med catheters are indicated for use in patients requiring administration of solutions, blood sampling, central venous pressure monitoring and injection of contrast media. The Vantex central venous catheters are indicated for use in patients requiring administration of solutions, blood sampling, central venous pressure monitoring and injection of contrast media. All catheters include a soft tip to reduce the risk of vessel perforation.
Comparative Analysis:	Verification and validation testing was conducted to compare the performance and functionality of the Multi-Med CVCs and Vantex CVCs to the predicate devices. This testing regimen included side-by-side comparative bench and pre-clinical performance testing of the pending and predicate devices. The results show that the performance functionality of the Multi-Med CVCs and Vantex CVCs and the pending guidewire is substantially equivalent to the predicate devices, and provides a marked improvement in the ease of use of the pending devices in comparison to the predicate devices. Thus, the Multi-Med CVCs and Vantex CVCs have been demonstrated to be safe and effective and substantially equivalent to the predicate devices for their intended use.
Functional/ Safety Testing:	The Multi-Med CVCs and Vantex CVCs have successfully undergone functional and performance testing, including bench studies, pre-clinical animal studies and biocompatibility testing. Multi-Med CVCs and Vantex CVCs have been shown to be safe and effective and substantially equivalent to the cited predicate devices for their intended use.
Conclusion:	The Multi-Med CVCs and Vantex CVCs are safe and effective and are substantially equivalent to the cited predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Marguerite Thomlinson, JD, BSME
Director of Regulatory Affairs
Edwards Lifesciences, LLC
One Edwards Way
Irvine, California 92614-5686

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Re: K113565
Trade/Device Name: Multi-Med Central Venous Catheters, Vantex Central Venous Catheters
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: April 16, 2012
Received: April 18, 2012

Dear Ms. Thomlinson:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113565

Device Name: Multi-Med Central Venous Catheters
Vantex Central Venous Catheters

Indications for Use:

The Multi-Med catheters are indicated for use in patients requiring administration of solutions, blood sampling, central venous pressure monitoring and injection of contrast media.

The Vantex central venous catheters are indicated for use in patients requiring administration of solutions, blood sampling, central venous pressure monitoring and injection of contrast media. All catheters include a soft tip to reduce the risk of vessel perforation.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for RZC May 16, 2012

Division Sign-Off)
)ivision of Anesthesiology, General Hospital
nfection Control, Dental Devices

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