JUN 1 3 2000

510(k) Summary, Safety and Effectiveness K992532

Submitter:	Edwards Lifesciences, LLC 17221 Red Hill Avenue Irvine, California 92614 USA
Contact:	Jason Smith Phone: 949-250-2662 Fax: 949-756-4021
Device Trade Name:	Vantex™ Central Venous Catheter with Oligon™ material with or without AMC™ Thromboshield™ coating
Common Name:	Central Venous Catheter
Classification:	Class II (Reference 21 CFR 880.5200
Predicate or Legally Marketed Device:	Multi-Med Multi-Lumen Central Venous Catheter with AMC™ Thromboshield™ and Arrow International's Central Venous Multi-Lumen Catheter with ARROWgard Blue
Date prepared:	July 27, 1999

Device Description

The Vantex™ Central Venous Catheter with Oligon™ material with or without AMC™ Thromboshield™ coating is a triple lumen central venous catheter constructed primarily from Oligon™ material. A soft, flexible tip is formed onto the distal tip of the catheter to reduce the potential for vessel perforation. Each lumen is intended for pressure monitoring, solution infusion, and blood sampling. The Vantex™ Central Venous Catheter with Oligon™ material with or without AMC™ Thromboshield™ coating is provided with injection caps to assist in maintaining lumen sterility and patency, removable slide clamps for each lumen extension, and integral and moveable suture loops for securing the catheter at the insertion site. The device will be packaged in a Barex tray sealed with a Tyvek lid and sterilized using 100% ethylene oxide.

Indications for Use:

The Vantex™ Central Venous Catheter with Oligon™ material with or without AMC™ Thromboshield™ is indicated for use in patients requiring pressure monitoring, infusion of solutions, and blood sampling in the central vein. All catheters are manufactured with a polyurethane-based Oligon™ antimicrobial polymer. The Oligon™ material uses silver as the antimicrobial agent.

Technology Comparison

The Vantex™ Central Venous Catheter with Oligon™ material with or without AMC™ Thromboshield™ is technologically comparable to the predicate devices in construction, materials, and physical specifications. Furthermore, design, manufacturing, and sterilization procedures are representative of current industry practices.

Test Summary, *In-vitro*

The non-clinical testing performed Vantex™ Central Venous Catheter with Oligon™ material with or without AMC™ Thromboshield™ included those set forth in the Draft Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters. The results of the *in vitro* testing demonstrate that the catheters meet the appropriate requirements of the ISO 10555-1 ("Sterile, single-use intravascular catheters -- Part 1: General requirements") and ISO 10555-3 ("Sterile, single-use intravascular catheters -- Part 3: Central venous catheters) standards.

Functional testing was performed on the Vantex™ Central Venous Catheter with Oligon™ material with or without AMC™ Thromboshield™ to evaluate the integrity and performance of the device. Based upon the results of this testing, the Edwards Lifesciences LLC, has determined that the Vantex™ Central Venous Catheter with Oligon™ material with or without AMC™ Thromboshield™ is safe and effective and is acceptable in design and construction for its intended use.

Further *in vitro* testing was conducted to verify the antimicrobial properties of the Vantex™ Central Venous Catheters with Oligon™ material with or without AMC™ Thromboshield™ coating. The results of this testing demonstrate that the Oligon™ material provides antimicrobial effectiveness (≥ 3 log reduction within 48 hours) against the following organisms commonly associated with catheter related infections: *Staphylococcus epidermidis, Staphylococcus aureus, Enterococcus faecalis, Candida albicans, Escherichia coli, Serratia marcescens, Acinetobacter calcoaceticus, Corynebacterium diptheriae, Enterobacter aerogenes, Klebsiella pneumoniae, GMRSa, and Pseudomonas aeruginosa.*

Test Summary, *In-vivo*

Clinical testing has been conducted in Canada to acquire safety data regarding silver, platinum, and benzalkonium chloride released from the Vantex™ Central Venous Catheters with Oligon™ material with or without AMC™ Thromboshield™ coating. The purpose of this study was to determine the safety of the Oligon™ material by evaluating the silver and platinum levels in blood serum prior to, during, and after catheter use and to determine the safety of the AMC™ Thromboshield™ coating by evaluating the bezalkonium chloride levels in blood serum prior to, during, and after use. Safe levels of silver, platinum, and benzalkonium were found in both blood serum and urine during this study.

Prior to market release of the product in Europe, a Marketing Evaluation was conducted to collect information on customer satisfaction with general performance characteristics of the Vantex™ Catheter. The clinicians expressed input as to the visibility of the catheter on a chest X-Ray. As a result of this feedback, Edwards Lifesciences modified the formulation of the Oligon™ material to include barium sulfate, which provides additional radiopacity to the catheter. The barium sulfate makes the radiopacity characteristic of the Vantex™ Catheters comparable to that of the predicate Baxter Multi-Med® Catheters.

Test Summary, Biocompatibility:

Biocompatibility testing was performed on the Vantex™ Central Venous Catheter with Oligon™ material with or without AMC™ Thromboshield™ (both Oligon™ formulations) in accordance with the requirements specified in International Standards Organization (ISO) 10993-1-1994 Biological Evaluation of Medical Devices - Part 1: Guidance on Selection of Tests and the FDA General Program Memorandum No. G95-1. The Vantex™ Central Venous Catheter with Oligon™ material with or without AMC™ Thromboshield™ (both Oligon™ formulations) was found to be biocompatible and nontoxic and acceptable for its intended use.

Rationale for Substantial Equivalence Determinations:

The battery of non-clinical and clinical tests discussed above demonstrates that Vantex™ Central Venous Catheter with Oligon™ material with or without AMC™ Thromboshield™ for both the original and barium-filled Oligon™ formulations exhibits comparable mechanical and functional specifications to the predicate devices in addition to being biocompatible and chemically acceptable. Based upon those characteristics, Vantex™ Central Venous Catheter with Oligon™ material with or without AMC™ Thromboshield™ is substantially equivalent to the predicate devices in safety and effectiveness in addition to being intended for the same uses.

Jason Smith
Regulatory Affairs Associate
Edwards Lifesciences LLC

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 7 - 2000

Mr. Jason Smith
Regulatory Affairs Associate
Edwards Lifesciences LLC
One Edwards Way
Irvine, California 92614

Re: K992532
Trade Name: Vantex™ Central Venous Catheter with OLIGON Material with or without AMC™ Thromboshield™ Coating
Regulatory Class: II
Product Code: FOZ
Dated: March 14, 2000
Received: March 8, 2000

Dear Mr. Smith:

This letter corrects our substantially equivalent letter of June 13, 2000, regarding the Regulatory Class.

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 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/dsma/dsmamain.html".

Sincerely,

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): K992532

Device Name: Vantex™ Central Venous Catheters with OLIGON™ material with or without AMC™ Thromboshield™ coating

Indications For Use:

The Vantex™ Central Venous Catheter with OLIGON™ with or without AMC™ Thromboshield™ coating are indicated for use in patients requiring ptessure monitoring, infusion of solutions, and blood sampling in the central vein. All catheters are manufactured with a polyurethane-based OLIGON™ antimicrobial polymer. The OLIGON™ material uses silver as the antimicrobial agent.

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

Concurrence of CDRH, Office Of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K992532