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510(k) SUMMARY

JUL - 2 2009

510(k) NUMBER: PENDING

510(k) OWNER: Mike Glennon
Vortex Medical Inc.50 Loring Drive
Norwell, MA 02061

CONTACT PERSON: Cheryl Blake
949-285-3517
949-448-7016 (fax)
e-mail cheryl.blake@interfaceusa.com

DATE OF PREPARATION: January 28, 2009

NAME OF DEVICE: Vortex Cannula

TRADE NAME: Not Determined

COMMON OR USUAL NAME:

CLASSIFICATION NAME: Catheter, Cannula and Tubing, Vascular, Cardiopulmonary Bypass

INDICATIONS FOR USE: Indications for Use: The Vortex Cannula is intended for use as a venous drainage cannula during extracorporeal bypass for up to 6 hours.

SUMMARY STATEMENT:

Identification of the legally marketed: The Vortex Cannula is substantially equivalent to the Estech Remote Access Perfusion Femoral Venous Cannula

Description:

The Vortex Cannula is a wire reinforced, ranging from 22 to 26 French, device that is of appropriate stiffness and flexibility so that it can be manipulated throughout the vascular system. The cannula is rigid enough to resist kinking, collapse and deformation that may compromise the lumen and inhibit flow through the cannula. The cannula has a proprietary distal end with a balloon activated, expandable, funnel-shaped tip that will enhance flow when the balloon is activated and will prevent clogging of the cannula with commonly encountered undesirable intravascular material that occurs with the predicate devices and facilitate en-bloc removal of such material from the vascular system. The cannula has a proximal end that can attach to a standard off the shelf extracorporeal circuit. The cannula will be shipped to the user in a sterile package and ready for use.

Non-clinical Testing: Bench top testing was conducted and comparisons were made to the predicated device.

Summary of Technological Characteristics: The Technological characteristics are the same as or equivalent to the predicated device and introduce no new safety and effectiveness issues when used as instructed.

Design Control / Risk Analysis/Design Verification: Design control, risk analysis and design verification activities for the subject of this Special 510(k) have been conducted in accordance with all applicable internal Design Procedures. The design control process employed is inclusive of the elements stipulated by 21 CFR § 820.30. The risk analysis preformed identified the risks relative to the performance requirements, as specified by ISO 14971and QSR and internal procedures for risk analysis. The Design Risk Assessment Profile was conducted in accordance to ISO 14971 and QSR internal Stand Operating Procedures, EN 1441 standards, ISO 9001/ISO 13485, AAMI/ISO TIR 14971, and 21 CFR § 820.30, validation and verification activities addressed the profile. Based on the risk analysis, validation and verification activities are formally controlled and addressed the activities included the methods, tests used, and acceptance criteria applied.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 2 2009

Vortex Medical Inc.
c/o Mr. Morten Simon Christensen
Staff Engineer & FDA Office Coordinator
Underwriters Laboratories, Inc.
455 Saginaw Drive
Redwood City, Ca 94063

Re: K091304
Vortex Cannula
Regulation Number: 21 CFR 870.4210
Regulation Name: Catheter, Cannula and Tubing, Vascular, Cardiopulmonary Bypass
Regulatory Class: Class II (two)
Product Code: DWF
Dated: June 17, 2009
Received: June 19, 2009

Dear Mr. Christensen:

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) 276-0120. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K091304

Indications for Use

510(k) Number (if known):_____

Device Name: VortexCannula

Indications for Use: The Vortex Cannula is intended for use as a venous drainage cannula during extracorporeal bypass for up to 6 hours.

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

510(k) Number K091304