K133445

MAR - 5 2014

510(k) SUMMARY

Device Name: AngioVac Cannula **Date Prepared:** March 3, 2014

A. Sponsor

Vortex Medical Inc.
26 Forest Street
Marlborough, MA 01752

B. Contact

Lorraine M. Hanley
Vice President of Global Regulatory Affairs
F: 508-658-7976
E: lorraine.hanley@navilyst.com

C. Device Name

Trade Name:	AngioVac Cannula
Common/Usual names:	Cardiopulmonary Bypass Venous Cannula Extraction Catheter
Classification Names:	Catheter, cannula and tubing, vascular, cardiopulmonary bypass 21 CFR§870.4210, ProCode DWF
Classification:	Class II

D. Predicate Device

Product	510(k)	Company
Vortex Cannula	K091304	Vortex Medical

E. Device Description

The AngioVac device is a 22 Fr cannula with a balloon-actuated, expandable, funnel shaped distal tip that can be advanced through a 26 Fr sheath over a guidewire into the venous system percutaneously or via a surgical cut-down. During use, the cannula is connected to an extracorporeal circuit and a commercially available pump head and bubble trap. A commercially available reinfusion cannula is placed for venous return (typically within internal jugular or one of the common femoral veins) and connected to the extracorporeal circuit. When the bypass pump is started, suction is created, removing blood and debris from around the tip of the AngioVac cannula, circulating the blood through the filter, and returns the blood to the patient via the venous return cannula. A benefit of the AngioVac Cannula is that it allows for removal of clot material, while minimizing blood loss via recirculation of blood through a standard extracorporeal (venovenous) bypass circuit. The device may be used in target vessels for thrombus/embolus extraction include, but are not limited to, the iliofemoral vein, Inferior Vena Cava (IVC), Superior Vena Cava (SVC) and Right Atrium (RA).

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F. Intended Use

The AngioVac Cannula is indicated for use as a venous drainage cannula during extracorporeal bypass for up to 6 hours. The cannula is also indicated for removal of fresh, soft thrombi or emboli during extracorporeal bypass for up to 6 hours.

G. Technology Characteristics

The proposed device has similar materials, design and components and technological characteristics as the predicate currently marketed AngioVac Cannula (K091304). The AngioVac Cannula is also similar to other devices used for removal of soft fresh thrombi or emboli such as the Pronto .035" Extraction Catheter (K070403 - Vascular Solutions) and the F.A.S.T. Funnel Catheter (K040010 - Genesis Medical, Inc.).

H. Performance Data

Bench and animal testing was performed to support substantial equivalence of the AngioVac Cannula when used for the removal of soft fresh thrombi or emboli. The AngioVac Cannula met all specified design and performance requirements. Additionally, the AngioVac Cannula has fulfilled the biocompatibility testing requirements identified in ISO 10993: Biological evaluation of medical devices Part 1: Evaluation and testing in the risk management process.

I. Clinical Testing

Not applicable

J. Conclusion

Based on results of in vitro and in vivo testing and responses to questions posed in the FDA's Decision Making Tree, the proposed device is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

March 5, 2014

Vortex Medical Inc.
Lorraine M. Hanley
Vice President of Global Regulatory Affairs
26 Forest Street
Marlborough, MA 01752

Re: K133445
Trade/Device Name: AngioVac Cannula
Regulation Number: 21 CFR 870.4210
Regulation Name: Catheter, cannula and tubing, vascular, cardiopulmonary bypass
Regulatory Class: Class II
Product Code: DWF
Dated: December 4, 2013
Received: December 5, 2013

Dear Ms. Lorraine Hanley:

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 contact 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. 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,

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

Enclosure

Indications for Use

510(k) Number (if known): K133445

Device Name: AngioVac Cannula

Indication For Use:

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Prescription Use ___X___ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)