510(k) Summary

DEC 16 2013

Summary of Safety and Effectiveness for the ClearGuard HD

General Information

Submitter
Pursuit Vascular, Inc.
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General Provisions

Trade Name	ClearGuard HD
Common/Usual Name	Hemodialysis Catheter Luer End Cap
Classification Name	21 CFR 880.5540
Predicate Devices	Boston Scientific Corporation Vaxcel™ Plus Chronic Dialysis Catheter

Device Description

The ClearGuard HD end cap is male luer lock end cap that incorporates an antimicrobial treatment on its surfaces. It is designed to reduce microbial colonization within a hemodialysis catheter hub.

The ClearGuard HD end cap consists of 1) a copolyester polymer plug, which has a rod extending from the luer region that is coated with the antimicrobial agent chlorhexidine acetate (CHA) and 2) a nylon lock ring with threads that are also coated with CHA. When a ClearGuard HD end cap is inserted into a liquid-filled catheter, CHA elutes into the catheter lock solution. This CHA solution is designed to reduce the number of microorganisms in the hemodialysis catheter hub.

The catheter extension line pinch clamps are used to maintain the lock solution within the catheter lumens and minimize the risk of air embolism. These clamps, which are closed when the catheter is not in use, mechanically confine the CHA and prevent diffusion of CHA toward the catheter tip and the patient's bloodstream.

Intended Use / Indications for Use

ClearGuard HD is indicated for use as an end cap for use with hemodialysis catheter hubs.

The antimicrobial treatment on the ClearGuard HD has been shown to be effective at reducing microbial colonization in hemodialysis catheter hubs against the following microorganisms: *Enterococcus faecium (VRE), Enterococcus faecalis (VRE), Acinetobacter baumannii, Escherichia coli, Staphylococcus aureus (MRSA), Staphylococcus aureus, Staphylococcus epidermidis (MRSE), Pseudomonas aeruginosa, Candida albicans* and *Candida parapsilosis* and has not been shown to be effective against *Candida paratropicalis* and *Klebsiella pneumoniae*.

The antimicrobial effectiveness was evaluated using *in vitro* methods and correlation between *in vitro* antibacterial activity and any clinical effectiveness has not been tested. It is not intended to be used for the treatment of existing infections. The antimicrobial is only effective within the hub of the catheter, and does not migrate to distal portions of the catheter.

Substantial Equivalence Comparison

The ClearGuard HD end cap is substantially equivalent to a legally marketed 510(k) cleared device in intended use, indications for use, principles of operation, hub compatibility, and the fact that they are both provided as sterile, non-pyrogenic, single use devices. The predicate device is a chronic hemodialysis catheter that contains end caps. The technological differences between ClearGuard HD end caps and the end caps of the predicate device include 1) the use of an antimicrobial agent on the end cap and 2) a rod extending 1.8 cm (0.7 in) from the luer region. The antimicrobial agent on the ClearGuard HD end cap is the same agent used on the Arrow Antimicrobial Pressure Injectable PICC reference device. This reference device has two versions of chlorhexidine applied to the catheter surfaces, chlorhexidine base and chlorhexidine acetate. The ClearGuard HD end cap has chlorhexidine acetate applied to the cap surfaces.

Results of design verification and validation testing demonstrate that the ClearGuard HD end cap is safe for use with hemodialysis catheters and reliably seals catheter hubs. It also demonstrates that the chlorhexidine antimicrobial agent effectively reduces the number of microorganisms in hemodialysis catheter hubs as does the reference Arrow PICC and introduces no new or increased safety concerns. The risk assessment results, together with the results of design verification and validation testing presented in this submission, confirm that the ClearGuard HD end cap raises no new questions of safety or effectiveness compared to the predicate and reference devices. The ClearGuard HD end cap has, therefore, been shown to be substantially equivalent to a legally marketed device for the purpose of 510(k) clearance.

Summary of Non-Clinical Testing

The ClearGuard HD end caps have been tested and compared to the predicate device. All data gathered demonstrate this device is substantially equivalent. No new or increased safety risks or efficacy issues have been raised.

Summary of Clinical Performance Data

Not applicable - no clinical data was needed to demonstrate substantial equivalence to its predicate device.

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

December 16, 2013

Pursuit Vascular, Inc.
Laurie E. Lynch, Ph.D.
Director Quality/Regulatory/Clinical
6901 E. Fish Lake Road, Suite 166
Maple Grove, MN 55369

Re: K131060
Trade/Device Name: ClearGuard HD End Cap
Regulation Number: 21 CFR§ 876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: II
Product Code: PEH
Dated: December 5, 2013
Received: December 6, 2013

Dear Laurie E. Lynch,

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,

Herbert P. Lerner -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K131060

Device Name
ClearGuard HD End Cap

Indications for Use *(Describe)*
ClearGuard HD is indicated for use as an end cap for use with hemodialysis catheter hubs.

The antimicrobial treatment on the ClearGuard HD has been shown to be effective at reducing microbial colonization in hemodialysis catheter hubs against the following microorganisms: *Enterococcus faecium (VRE), Enterococcus faecalis (VRE), Acinetobacter baumannii, Escherichia coli, Staphylococcus aureus (MRSA), Staphylococcus aureus, Staphylococcus epidermidis (MRSE), Pseudomonas aeruginosa, Candida albicans and Candida parapsilosis* and has not been shown to be effective against *Candida paratropicalis* and *Klebsiella pneumoniae*.

The antimicrobial effectiveness was evaluated using *in vitro* methods, and correlation between *in vitro* antibacterial activity and any clinical effectiveness has not been tested. The subject device is not intended to be used for the treatment of existing infections. The antimicrobial is only effective within the hub of the catheter, and does not migrate to distal portions of the catheter.

Herbert P. Lerner -S
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Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*