May 25, 2018

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

Re: K180111
Trade/Device Name: ClearGuard® HD Antimicrobial Barrier Cap
Regulation Number: 21 CFR§ 876.5540
Regulation Name: Blood Access Device and Accessories
Regulatory Class: II
Product Code: PEH
Dated: April 27, 2018
Received: April 30, 2018

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.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Charles Viviano -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180111

Device Name
ClearGuard HD Antimicrobial Barrier Cap

Indications for Use *(Describe)*
ClearGuard HD Antimicrobial Barrier Cap is indicated for use with hemodialysis catheter hubs.

Using in vitro methods, the antimicrobial treatment on the ClearGuard HD Antimicrobial Barrier Cap 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.

Using post-market clinical surveillance data, use of the ClearGuard HD Antimicrobial Barrier Cap has been shown to reduce the incidence of central-line associated bloodstream infections (CLABSI) in hemodialysis patients with catheters. Note: CLABSI was defined as a positive blood culture (PBC) not related to an alternative source of infection per the National Healthcare Safety Network (NHSN) surveillance definition. Alternative sources were excluded if dialysis sites attributed the PBC to vascular access on the dialysis event form. The actual reduction in CLABSI rates may be less substantial as the evaluation for alternative PBC sources was not pre-specified, nor standardized between patients and clinical sites, and supplemental data evaluating for alternative sources were not available for review.

The subject device is not intended to be used for the treatment of existing infections. The antimicrobial is only present within the hub of the catheter and does not migrate to distal portions of the catheter.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Date Prepared: 21-May-2018

Submitter's Name / Contact Person

Manufacturer	**Contact Person**
Pursuit Vascular, Inc. 6901 E. Fish Lake Road, Suite 166 Maple Grove, MN 55369	Laurie Lynch, PhD Director of Quality/Regulatory/Clinical Phone: (952) 221-2468 Fax: (763) 592-8202 Email : llynch@pursuitvascular.com

General Information

Trade Name	ClearGuard® HD Antimicrobial Barrier Cap
Common / Usual Name	Hemodialysis Catheter Luer End Cap
Regulation Name	21 CFR 876.5540; Blood Access Device and Accessories
Product Code	PEH; Hemodialysis Catheter Luer End Cap
Device Class	II
Predicate Devices	K131060 ClearGuard HD End Cap

Device Description

The ClearGuard HD Antimicrobial Barrier Cap (hereinafter also referred to as the ClearGuard HD cap) is a single-use male luer lock cap that incorporates an antimicrobial treatment on its surfaces.

The ClearGuard HD cap consists of 1) a polypropylene 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 cap is inserted into a liquid-filled catheter, CHA elutes from the rod into the catheter lock solution. This CHA solution is designed to kill microorganisms in the hemodialysis catheter hub, which results in a reduction in Central Line-Associated Bloodstream Infection (CLABSI) rates.

The catheter extension line pinch clamps are used to maintain the lock solution within the catheter lumens to minimize the risk of air embolism and maintain catheter patency. 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 Antimicrobial Barrier Cap is indicated for use with hemodialysis catheter hubs.

Using *in vitro* methods, the antimicrobial treatment on the ClearGuard HD Antimicrobial Barrier Cap 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),

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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*.

Using post-market clinical surveillance data, use of the ClearGuard HD Antimicrobial Barrier Cap has been shown to reduce the incidence of central-line associated bloodstream infections (CLABSI) in hemodialysis patients with catheters. Note: CLABSI was defined as a positive blood culture (PBC) not related to an alternative source of infection per the National Healthcare Safety Network (NHSN) surveillance definition. Alternative sources were excluded if dialysis sites attributed the PBC to vascular access on the dialysis event form. The actual reduction in CLABSI rates may be less substantial as the evaluation for alternative PBC sources was not pre-specified, nor standardized between patients and clinical sites, and supplemental data evaluating for alternative sources were not available for review.

The subject device is not intended to be used for the treatment of existing infections. The antimicrobial is only present within the hub of the catheter and does not migrate to distal portions of the catheter.

Substantial Equivalence Comparison
The predicate device is the Pursuit Vascular, Inc. ClearGuard HD End Cap, K131060.

In regard to the technological characteristics, the predicate and subject devices are both antimicrobial coated hemodialysis catheter caps manufactured by the same company, Pursuit Vascular, Inc. See comparison of the subject and predicate device in Table 1 below.

Table 1. Comparison of Subject and Predicate Devices

	Subject Device	**Predicate Device**
510(k) Number	K180111	K131060
Classification	Class II; PEH; 21 CFR 876.5540; Blood access device and accessories	Class II; PEH; 21 CFR 876.5540; Blood access device and accessories
Indications for Use	ClearGuard HD Antimicrobial Barrier Cap is indicated for use with hemodialysis catheter hubs. Using *in vitro* methods, the antimicrobial treatment on the ClearGuard HD Antimicrobial Barrier Cap 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*	ClearGuard HD is indicated for use as an end cap for use with hemodialysis catheter hubs. The antimicrobial treatment on the ClearGuard HD end cap 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

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	Subject Device	Predicate Device
	aeruginosa, Candida albicans and *Candida parapsilosis* and has not been shown to be effective against *Candida paratropicalis* and *Klebsiella pneumoniae.* Using post-market clinical surveillance data, use of the ClearGuard HD Antimicrobial Barrier Cap has been shown to reduce the rate of central line-associated bloodstream infections (CLABSI) in hemodialysis patients with catheters. **Note:** CLABSI was defined as a positive blood culture (PBC) not related to an alternative source of infection per the National Healthcare Safety Network (NHSN) surveillance definition. Alternative sources were excluded if dialysis sites attributed the PBC to vascular access on the dialysis event form. The actual reduction in CLABSI rates may be less substantial as the evaluation for alternative PBC sources was not pre-specified, nor standardized between patients and clinical sites, and supplemental data evaluating for alternative sources were not available for review. The subject device is not intended to be used for the treatment of existing infections. The antimicrobial is only present within the hub of the catheter and does not migrate to distal portions of the catheter.	*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.
Materials/Design		
Maximum amount of chlorhexidine on the device	2.53 mg	2.43 mg
Maximum amount of chlorhexidine that is potentially released to the patient	0.6 mg	0.6 mg
Lock Ring	Nylon with red or blue dye	Nylon with red or blue dye

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	Subject Device	Predicate Device
Plug	• Polypropylene with new white colorant • Specify minimum and maximum surface roughness • Fins to prevent lock ring from rotating	• Polyester with white colorant • Specify maximum luer surface roughness • No fins, lock ring freely rotates
Shield	• Polypropylene with white colorant	• Polyester with white colorant
Packaging, Sterilization, Shelf Life		
Packaging	Foil pouch	Foil pouch
Sterilization	Gamma, SAL 10^{-6}	Gamma, SAL 10^{-6}
Device shelf life	3 years	11 months

Summary of Non-Clinical Testing

The ClearGuard HD Antimicrobial Barrier Caps have been found to be safe and effective for their intended use. Finished sterile ClearGuard HD Antimicrobial Barrier Caps have been subjected to biocompatibility testing and found to be non-hemolytic, non-cytotoxic, non-irritating, non-sensitizing, non-mutagenic, non-toxic and non-pyrogenic under intended use conditions. The ClearGuard Antimicrobial Barrier Caps have also met their requirements for liquid leakage, disassembly torque, plug, shield and pouch integrity, and for antimicrobial quantity, effectiveness, elution and solubility, initially, and after 3 years real time shelf life.

Biocompatibility testing was conducted in compliance with ISO 10993-1:2009/TC1 2010 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process. Package integrity was conducted in compliance with ASTM D3078-02(2013) Standard Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission.

Clinical Trial Results

A 13-month, prospective, cluster-randomized, multi-arm, unblinded clinical study with a control was conducted at 40 dialysis facilities throughout the United States only. Facilities were pair-matched and randomly assigned to treatment or control group. The treatment group received the ClearGuard HD Antimicrobial Barrier Cap and the control group received the Tego® Connector with the Curos™ Disinfecting Cap. The primary study endpoint was PBC rate. There were no other primary study endpoints but an ad hoc exploratory analysis of CLABSI was also conducted. 1,671 subjects participated in the study during the primary and exploratory analyses, accruing approximately 183,000 CVC-days in the primary analysis.[1] The subject enrollment is shown in Table 2 and the subject demographics are shown in Table 3.

Table 2. Subject Enrollment During the Intervention Period

Stage	Investigation Device Arm (ClearGuard HD)	Control Device Arm (Tego+Curos)	Total in Both Arms
Subjects enrolled	951	960	1911

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Stage	Investigation Device Arm (ClearGuard HD)	Control Device Arm (Tego+Curos)	Total in Both Arms
Subjects excluded for history of heparin allergy	9	0	9
Subjects receiving treatment	942	960	1902
Subjects excluded due to treatment ≤21 days	116	115	231
Subjects in primary and exploratory analyses	826	845	1671

Table 3. Subject Demographics During the Intervention Period

Characteristic	All	Treatment Group	Control Group	P-Value
No. of Facilities	40	20	20	
No. of CVC Subjects	1671	826	845	
Age, y	62.8 ± 14.9	63.7 ± 14.4	62.0 ± 15.3	0.02
Gender (% Male)	856 (51)	421 (51)	435 (51)	0.8
Race				<0.001
Caucasian	778 (47)	414 (50)	364 (43)	
African American	621 (37)	267 (32)	354 (42)	
Hispanic	171 (10)	83 (10)	88 (10)	
Other	98 (6)	60 (7)	38 (5)	
Missing	3 (0)	2 (0)	1 (0)	
Diabetes	998 (60)	477 (58)	521 (62)	0.1
Dialysis vintage, y	1.7 ± 3.2	1.6 ± 3.3	1.8 ± 3.2	0.2

Note: Values for categorical variables are given as number (percentage); values for continuous variables, as mean ± standard deviation.

As is standard policy at the participating facilities, blood culture results were reported into the electronic health record in automated fashion and to the National Healthcare Safety Network (NHSN) Dialysis Event (DE) Form, from which they were abstracted for analysis.

The pre-specified primary study endpoint was PBC rate. This study demonstrated that use of the ClearGuard HD Antimicrobial Barrier Caps resulted in a statistically significant reduction in the rate of PBCs compared to the use of Tego connector plus Curos cap in hemodialysis patients with catheters. See Table 4 below.

Table 4. Randomized Clinical Study Results Primary Analysis: PBC rates of ClearGuard HD vs. Tego+Curos on a Per-Event Basis

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Variable	Result
PBC Rate, ClearGuard HD	0.28 per 1,000 CVC-days
PBC Rate, Tego+Curos	0.75 per 1,000 CVC-days
Incidence Rate Ratio (IRR)	0.37
Reduction in PBC Rate	63%
P value	0.001

The exploratory ad-hoc CLABSI analysis was conducted to explore the possible reduction of a more clinically meaningful outcome than PBC rates. However, this analysis was not pre-specified in the protocol and may have limitations (see Note below).

For a PBC to be classified as a CLABSI in this study per the NHSN surveillance definition, it must have been a Laboratory-Confirmed Bloodstream Infection (LCBI)[2] as follows: LCBI1) a recognized pathogen (an organism not included on the NHSN common commensal list) identified from one or more blood specimens obtained by blood culture microbiologic testing and the organism(s) identified in the blood must not be related to an infection at another site (as indicated by the "vascular access" box being checked as the suspected source of the PBC on the Dialysis Event (DE) form)[3], OR an LCBI2) the same NHSN common commensal identified by blood culture microbiologic testing from two or more blood specimens drawn on the same day, the organism(s) identified in blood must not be related to an infection at another site (as indicated by the "vascular access" box being checked as the suspected source of the PBC on the DE form), and the subject had at least one of the following symptoms: fever, chills, or hypotension (as indicated on the DE form). Also, the CLABSI analysis was conducted on a per-subject basis (i.e., censored the patient after the first CLABSI event to prevent potentially double counting the same infection). All cultures were processed by a single clinical laboratory. Note: CLABSI was defined as a positive blood culture (PBC) not related to an alternative source of infection per the National Healthcare Safety Network (NHSN) surveillance definition. Alternative sources were excluded if dialysis sites attributed the PBC to vascular access on the dialysis event form. The actual reduction in CLABSI rates may be less substantial as the evaluation for alternative PBC sources was not pre-specified, nor standardized between patients and clinical sites, and supplemental data evaluating for alternative sources were not available for review.

The CLABSI analysis demonstrated that using ClearGuard HD Antimicrobial Barrier Caps resulted in a reduction in the rate of CLABSIs compared to the control (Table 5).

Table 5. Randomized Clinical Study Results Exploratory Analysis: CLABSI Rates of ClearGuard HD vs. Tego+Curos on a Per-Subject Basis

Variable	Result
CLABSI Rate, ClearGuard HD	0.17 per 1,000 CVC-days
CLABSI Rate, Tego+Curos	0.50 per 1,000 CVC-days
Incidence Rate Ratio (IRR)	0.34
Reduction in CLABSI Rate	66%

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There was no formal safety endpoint associated with this clinical study. There were no device-associated adverse events reported via the FDA's medical device reporting (MDR) during this study or in a previous study.[4]

Conclusions

Results of design verification and validation testing demonstrate that 1) the ClearGuard HD Antimicrobial Barrier Cap is safe for its intended use as an end cap for hemodialysis catheters and 2) the chlorhexidine antimicrobial agent effectively reduces the number of microorganisms in hemodialysis catheter hubs following three years of real time ambient aging. The risk assessment results, together with the results of design verification and validation testing presented in this submission, confirm that the ClearGuard HD Antimicrobial Barrier Cap raised no new questions of safety or effectiveness compared to the predicate device. The ClearGuard HD Antimicrobial Barrier Cap has, therefore, been shown to be substantially equivalent to a legally marketed device for the purpose of 510(k) clearance. The post-market clinical study demonstrated a reduction in the rate of CLABSIs with use of the device, thus supporting the expanded indications for use.

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[1] Brunelli, SM MD, MSCE, Van Wyck, DB MD, Njord, L PhD, Killion, DP MBA, Lynch, LE, PhD and Ziebol, RJ BS. Cluster-Randomized Trial of Devices to Prevent Catheter-Related Bloodstream Infection. J Am Soc Nephrol; 29:1336-1343, 2018.

[2] Centers for Disease Control and Prevention (CDC): National Healthcare Safety Network (NHSN) Patient Safety Component Manual, January 2018. Bloodstream Infection Event. Chapter 4 Device-associated Module: Central Line-Associated Bloodstream Infection and Non-central Line Associated Bloodstream Infection). https://www.cdc.gov/nhsn/pdfs/pscmanual/pcsmanual_current.pdf. Accessed Apr 23, 2018.

[3] https://www.cdc.gov/nhsn/forms/57.502_DIAL_BLANK.pdf. Accessed Apr 23, 2018.

[4] Hymes JL, Mooney A, Van Zandt C, Lynch L, Ziebol R, Killion D: Dialysis catheter-related bloodstream infections: a cluster-randomized trial of the ClearGuard HD antimicrobial barrier cap. Am J Kidney Dis 69(2): 220-227, 2017.