January 3, 2020

PICCGuard LLC
% E.J. Smith
Consultant
Smith Associates
1468 Harwell Avenue
Crofton, Maryland 21114

Re: K191195
Trade/Device Name: PICCGuard
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: Class II
Product Code: PZW, LJS, FPA
Dated: December 3, 2019
Received: December 4, 2019

Dear E.J. Smith:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Geeta Pamidimukkala
Acting Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of Gastrorenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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)*
K191195

Device Name
PICCGuard

Indications for Use *(Describe)*
The PICCGuard device is indicated for use as a tamper evident enclosure for the shaft of the catheter and Luer hub with needleless connector attached on medical devices such as PICC lines and other central line catheter ports.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Company Name:	PICCGuard LLC
Address:	P.O. Box 1235
City:	Sheboygan
State:	WI 53082
Contact Person:	Katie Justus
	President
Phone:	918-519-2563
Email:	info@piccguard.com

Summary Preparation Date: December 11, 2019

Device Name:	PICCGuard
Common/Usual Name:	Catheter Access Cover, Tamper Resistant
Classification Name:	Catheter, Intravascular, Therapeutic, Long-Term Greater than 30-Days
Regulation Number:	21 CFR 880.5970
Primary Product Code:	PZW
Secondary Product Code:	LJS, FPA
Device Class:	Class II
Panel:	General Hospital Branch

PREDICATE DEVICE:

	Manufacturer	Brand Name	510(k) Number
Primary	Vygon	5 Fr DL PowerPICC® Catheter	K172899
Reference	International Medical Industries, Inc.	Tamper Evident Cap with Male Luer Lock	K182545

DEVICE DESCRIPTION:

The PICCGuard is a two-piece plastic housing with locking barb that inserts through a hole in the bottom housing. After inserting the shaft of the catheter and Luer hub with needleless connector attached, the two halves slide together, and the barb is pushed through the hole in the bottom housing. Once the barb is inserted, the housing is locked. When a healthcare provider needs intravenous access, medical scissors can be used to disconnect the lid from the locked portion. The PICCGuard is then removed giving access to the needleless connector, and the health care provider can administer medications per normal routine.

INDICATIONS FOR USE

The PICCGuard device is indicated for use as a tamper evident enclosure for the shaft of the catheter and Luer hub with needleless connector attached on medical devices such as PICC lines and other central line catheter ports.

PREDICATE PRODUCT COMPARISON TABLE (Primary)

	PICCGuard	Vygon	Comments
Brand Name	PICCGuard	5 Fr DL PowerPICC® Catheter	
Regulatory Class	21 CFR 880.5970	21 CFR 880.5970	Substantially Equivalent
Classification Name	Percutaneous, implanted, long-term intravascular catheter	Percutaneous, implanted, long-term intravascular catheter	Substantially Equivalent
Product Code	PZW, LJS, FPA	LJS	Different
Review Panel Division	General Hospital	General Hospital	Substantially Equivalent
Intended Use	The PICCGuard device is indicated for use as a tamper evident enclosure for the shaft of the catheter and Luer hub with needleless connector attached	The catheters are intended for short or long term peripheral access to the central venous system for intravenous therapy and blood	Different See Technological Characteristics

	PICCGuard	Vygon	Comments
	on medical devices such as PICC lines and other central line catheter ports.	sampling.	
Use Environment	Hospitals and Clinics	Hospitals and Clinics	Substantially Equivalent
Patient Population	Patients requiring a long-term central line catheter	Patients requiring a long-term central line catheter	Substantially Equivalent

Discussion of Differences: The PICCGuard differs from the predicate Vygon 5 Fr DL PowerPICC® in that the PICCGuard is an accessory to an intravascular catheter, and is designed to be used over the catheter to provide indication to the health care provider when unauthorized access of a catheter may have occurred by securely encasing the non-sterile Luer hub(s) placed on catheter lines. Additionally, the product code PZW reflects that the PICCGuard is an accessory to a catheter, product code LJS and FPA.

Technological Characteristics

The PICCGuard is an accessory to the predicate device and provides the predicate device with a tamper evident feature to alert the HCP of tampering.

The normal standards testing, functional testing, biocompatibility testing, sterilization and shelf-life studies of a Catheter, Intravascular, Therapeutic, Long-Term Greater than 30-Days are not applicable to the PICCGuard medical device.

PICCGuard conducted ISO 10993-5 cytotoxicity, ISO 10993-10 sensitization and ISO 10993-10 irritation studies, which satisfy the biocompatibility requirements of ISO 10993-1 for surface device with intact skin contact and contact duration >30d.

PICCGuard successfully conducted functionality testing for the 3 key elements for PICCGuard features, 1) confirm tamper evident, 2) repeated removal a central line catheter to demonstrate no leakage for repeated assemblies, disassembles, and flush cycles of the central-line catheter and 3) ease-of-use using medical scissors to remove the PICCGuard . These functionality tests demonstrate the performance of the PICCGuard and raises no new issues of safety and effectiveness in use with a central line catheter.

The PICCGuard is sold non-sterile versus a central line catheter which is sold sterile. The PICCGuard does not come into direct contact with the open Luer port. The PICCGuard houses the catheter shaft and needleless connector which are considered non-sterile. The non-sterile feature of the PICCGuard, housing the non-sterile catheter shaft and needleless connector raises no new issues of safety and effectiveness.

In support of our indications for use statement and principle of operations the reference predicate has a similar indication for use and principle of operations of the tamper evident claim and tamper evident method. The reference predicate is also used as an accessory to a medical device used in the delivery of intravenous I.V. solutions and drugs.

NONCLINICAL PERFORMANCE TESTING

- ISO 10993-5 Third Edition 2009-06-01 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (Fluid Extraction/L929 Mouse Fibroblast)
- ANSI/AAMI/ISO 10993-10:2010(R)2014 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization (Guinea Pig Maximization Test (0.9% NaCl)
- ANSI/AAMI/ISO 10993-10:2010(R)2014 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization (Cottonseed Oil)
- ANSI/AAMI/ISO 10993-10:2010(R)2014 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization (0.9% NaCl and CSO Extracts)
- ISO 10993-1 Fourth edition 2009-10-15 Biological evaluation of medical devices – Part 1: Evaluation and testing within a management process
- ISO 14971 Second addition 2007-03-01 Medical devices – Application of risk management to medical devices
- ISO 10555-1:2013; Intravascular catheters – sterile single-use catheters – Part 1: General requirements*, Annex C* (used in our functionality testing)

Biocompatibility Tests Summary and of Results

Standard Number	Description	Conclusion
ISO 10993-5 Third edition 2009-06-01	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (Fluid Extraction/L929 Mouse Fibroblast)	Under the conditions of this study, the Test Article meets test acceptance criteria
ANSI AAMI ISO 10993-10:2010/(R)2014	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization (Guinea Pig Maximization Test (0.9% NaCl)	Under the conditions of this study, the test article is a Non-sensitizer.
ANSI AAMI ISO 10993-10:2010/(R)2014	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization (Cottonseed Oil)	Under the conditions of this study, the test article is a Non-sensitizer.
ANSI AAMI ISO 10993-10:2010/(R)2014	Biological evaluation of medical devices - Part 10:	Under the conditions of this study. The Test Article Passes

Standard Number	Description	Conclusion
	Tests for irritation and skin sensitization (0.9% NaCI and CSO Extracts)	

Functional Testing Results Summary Table

Test	Acceptance Criteria	Pass/Fail
Removal of Device to Confirm Tamper Evident	The device shall show signs of being tamper with and shall break near the locking tab.	All samples Passed
Repeated Removal of PICCGuard from PICC lines	The catheter shows no sign of leakage after assemble / disassemble / flush cycles.	All samples Passed
Removable of Wings by Medical Scissors	The tabs of the device shall easily be cut by medical scissors	All samples Passed

CLINICAL STUDIES:

No clinical studies were conducted.

CONCLUSION:

The comparative review of PICCGuard used as an accessory to a central line catheter is substantially equivalent to the predicate device