February 26, 2018

Vygon USA
Jillian Mikovich
Regulatory Affairs Manager
2750 Morris Rd, Suite A200
Lansdale, Pennsylvania 19460

Re: K172899
Trade/Device Name: Vygon PICCs
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: Class II
Product Code: LJS
Dated: January 26, 2018
Received: January 29, 2018

Dear Jillian Mikovich:

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,

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental 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)*
K172899

Device Name

Vygon PICCs

Indications for Use *(Describe)*

The catheter is indicated for short or long term peripheral access to the central venous system for intravenous therapy, power injection of contrast media, and allow(s) for central venous pressure monitoring. For blood sampling, infusion or therapy, use 4 French or larger catheter. The maximum recommended infusion rate is 5mL/sec for power injection of contrast media. For central venous pressure monitoring, it is recommended that catheter lumen of 20 gauge or larger be used.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K172899
510(k) Summary (21 CFR 807.92(c))

I. Submitter Information

Submitter Name:	Vygon
Address:	2750 Morris Road, Suite A200 Lansdale, PA 19446
Telephone:	215-390-2002
Fax:	215-672-6740
Contact Person:	Jillian Mikovich
Email of Contact:	jmikovich@vygonus.com
Date Prepared:	February 23, 2018

II. Device

Device Name:	Vygon PICCs
Common Name:	Vygon PICCs
Common/Usual Name:	Peripherally Inserted Central Catheter (PICC)
Classification Name:	Percutaneous, Implanted, Long-Term Intravascular Catheter
Classification Panel:	General Hospital
Regulation Device Name:	Catheter, Intravascular, Therapeutic, Long-Term Greater Than 30 Days
Regulation Number:	21 CFR 880.5970
Regulatory Class:	2
Product Code:	LJS

III. Predicate Device

Predicate Name:	5 Fr DL PowerPICC® Catheter
Trade Name:	5 Fr DL PowerPICC® Catheter
Common/Usual Name:	Peripherally Inserted Central Catheter (PICC)
Classification Name:	LJS - Percutaneous, Implanted, Long-Term Intravascular Catheter
Premarket Notification:	K051672
Manufacturer:	Bard Access Systems, Inc.

Per the FDA Medical Device Recalls Database, this predicate has not been subject to a design related recall.

IV. Indications for Use

The catheter is indicated for short or long term peripheral access to the central venous system for intravenous therapy, power injection of contrast media, and allow(s) for central venous pressure monitoring. For blood sampling, infusion or therapy, use 4 French or larger catheter. The maximum recommended infusion rate is 5mL/sec for power injection of contrast media. For central venous pressure monitoring, it is recommended that catheter lumen of 20 gauge or larger be used.

The Indications for Use statement for the Vygon PICCs is not identical to the predicate device, 5 Fr DL PowerPICC® Catheter, Indications for Use; however, the differences do not alter the intended therapeutic use of the device. Both the subject and predicate devices have the same intended use for short or long term peripheral access to the central venous system for intravenous therapy and blood sampling.

V. Technological Characteristics

All characteristics of the Vygon PICCs are substantially equivalent to the predicate device, the Bard Access Systems 5 Fr DL PowerPICC® catheter. Both the subject and the predicate catheters are sterile, single-use, polyurethane PICCs with the same intended use, indications for use, similar design, similar sizes, similar or the same materials, and similar properties. See comparison table below.

Attribute	Predicate: Predicate Device DL	Subject Device 1 SL	Subject Device 2 DL	Subject Device 3 TL
Device Name	5 Fr DL PowerPICC® Catheter	Vygon PICC 4 Fr SL	Vygon PICC 5 Fr DL	Vygon PICC 6 Fr TL
510(k) Number	K051672	K172899	K172899	K172899
510(k) Submitter	Bard Access Systems (BAS)	Vygon USA	Vygon USA	Vygon USA
Trade Name	5 Fr DL PowerPICC® Catheter	Vygon PICC 4 Fr SL	Vygon PICC 5 Fr DL	Vygon PICC 6 Fr TL
Common Name	Peripherally Inserted Central Catheter (PICC)	Same as Predicate	Same as Predicate	Same as Predicate

Attribute	Predicate: Predicate Device DL	Subject Device 1 SL	Subject Device 2 DL	Subject Device 3 TL
Device Name	5 Fr DL PowerPICC® Catheter	Vygon PICC 4 Fr SL	Vygon PICC 5 Fr DL	Vygon PICC 6 Fr TL
Classification Name	Catheter, Intravascular, Therapeutic, Long-Term Intravascular Catheter	Same as Predicate	Same as Predicate	Same as Predicate
Regulatory Class	2	Same as Predicate	Same as Predicate	Same as Predicate
Classification Regulation	21 CFR 880.5970	Same as Predicate	Same as Predicate	Same as Predicate
Product Code	LJS	Same as Predicate	Same as Predicate	Same as Predicate
Review Panel / Division	General Hospital	Same as Predicate	Same as Predicate	Same as Predicate
Indications for Use	The PowerPICC® catheter is indicated for short or long term peripheral access to the central venous system for intravenous therapy and power injection of contrast media. For blood sampling, infusion or therapy, use a 4 French or larger catheter. The maximum recommended infusion rate is 5ml/see for power injection of contrast media. The maximum pressure of power injectors used with the PowerPICC®	The catheter is indicated for short or long term peripheral access to the central venous system for intravenous therapy, power injection of contrast media, and allow(s) for central venous pressure monitoring. For blood sampling, infusion or therapy, use 4 French or larger catheter. The maximum recommended infusion rate is 5mL/sec for power injection of contrast media. For central venous pressure monitoring, it is recommended that	The catheter is indicated for short or long term peripheral access to the central venous system for intravenous therapy, power injection of contrast media, and allow(s) for central venous pressure monitoring. For blood sampling, infusion or therapy, use 4 French or larger catheter. The maximum recommended infusion rate is 5mL/sec for power injection of contrast media. For central venous pressure monitoring, it is recommended that	The catheter is indicated for short or long term peripheral access to the central venous system for intravenous therapy, power injection of contrast media, and allow(s) for central venous pressure monitoring. For blood sampling, infusion or therapy, use 4 French or larger catheter. The maximum recommended infusion rate is 5mL/sec for power injection of contrast media. For central venous pressure monitoring, it is recommended that

Attribute	Predicate: Predicate Device DL	Subject Device 1 SL	Subject Device 2 DL	Subject Device 3 TL
Device Name	5 Fr DL PowerPICC® Catheter	Vygon PICC 4 Fr SL	Vygon PICC 5 Fr DL	Vygon PICC 6 Fr TL
	catheter may not exceed 300 psi.	catheter lumen of 20 gauge or larger be used.	catheter lumen of 20 gauge or larger be used.	catheter lumen of 20 gauge or larger be used.
Intended Use	The catheters are intended for short or long term peripheral access to the central venous system for intravenous therapy and blood sampling.	Same as Predicate	Same as Predicate	Same as Predicate

Table 1: Substantial Equivalence Comparison Table

VI. Performance Testing

Vygon PICCs were tested per Table 2 and Table 3 below.

Special controls for the Product Code LJS include the guidance document "Guidance on Premarket Notification [510(K)] Submissions for Short-Term and Long-Term Intravascular Catheters" and the consensus standards:

- ISO 10555-1 Second edition 2013-06-15 Intravascular catheters -- Sterile and single-use intravascular catheters -- Part 1: General requirements
- ISO 10555-3 Second edition 2013-06-15 Intravascular catheters -- Sterile and single-use catheters -- Part 3: Central venous catheters

- ISO 10555-1 and ISO 10555-3 requirements have been addressed and met.

Other requirements listed in the guidance document "Guidance on Premarket Notification [510(K)] Submissions for Short-Term and Long-Term Intravascular Catheters" have been met in the development of the device and are described below.

Bench Testing

Bench tests are listed below.

Standard	Sterile Device Test	Result
ISO 9626:2016	Dimensional Inspections	Passed
ISO 10555-1:2014	Catheter Conditioning (Saline)	Passed
ISO 10555-1:2014	Leak Test	Passed
Internal Requirement	Priming Volume Test	Passed
ISO 10555-1:2014	Gravity Flow Test	Passed
ISO 10555-1:2014	Pump Flow Test	Passed
ISO 10555-1:2014	Tensile Test	Passed
ISO 10555-1:2014	Burst Test	Passed
ISO 10555-1:2014	Power Injection Conditioning	Passed
Internal Requirement	Printing Font Size	Passed
ASTM F1842-15	Ink Permanence	Passed
ISO 594-1: 1986 Via ISO 80369-7:2016 Functional Testing	Luer Taper Test	Passed
ASTM F1842-15	Ink Integrity Test	Passed
Vygon Internal Requirement	Aspiration Flow Test	Passed
Vygon Internal Requirement	Luer Color/Orientation Test	Passed
Vygon Internal Requirement	Clamp Closure Maintenance Test	Passed
Vygon Internal Requirement	Clamp and ID Tag Fit Test	Passed
Vygon Internal Requirement	Clamp Actuation Test	Passed

Table 2: Vygon PICCs Performance Testing

Standard	Sterile, Aged (Accelerated 12 Months) Device Test	Result
ISO 10555-1:2014	Power Injection Conditioning	Passed
ISO 10555-1:2014	Burst Test	Passed

Table 3: Vygon PICCs Aged Performance Testing

Sterilization Testing

Sterilization tests are listed in Table 4 and Table 5 below.

Standard	Sterile, Aged (Accelerated 13 Months) Packaging Test	Result
ASTM F88 / F88M-15	Seal Strength	Passed

ASTM F2096-11	Bubble Leak	Passed

Table 4: Vygon PICCs Aged Packaging Testing

Standard	Sterile Device Test	Result
ANSI/AAMI ST72:2011	LAL Testing	Passed
ISO 10993-7:2008	EO Residual Testing	Passed

Table5: Vygon PICCs Sterile Testing

In addition, performance testing for catheter stiffness and catheter flexural fatigue tolerance was completed on the final finished sterile devices with acceptable results.

Clinical Testing

No clinical testing was performed.

Biocompatibility Testing

Biocompatibility tests are listed below in Table 6.

Standard	Test Name	Result
ISO 10993-5:2009/(R)2014	Cytotoxicity	Non-cytotoxic
AAMI/ANSI/ISO 10993-10:2010/(R)2014	Sensitization	Non-sensitizer
AAMI/ANSI/ISO 10993-10:2010/(R)2014	Irritation	Non-irritant
ISO 10993-11:2006	Acute Systemic Injection	Non-toxic
USP37	Material Mediated Pyrogen	Non-pyrogenic
ISO 10993-4: 2002/(R) 2013 & A1: 2006/ (R) 2013	Hemolysis (extract)	Non-hemolytic
ISO 10993-4: 2002/(R) 2013 & A1: 2006/ (R) 2013	Hemolysis (direct)	Non-hemolytic
ISO 10993-4: 2002/(R) 2013 & A1: 2006/ (R) 2013	Complement Activation Predicate: PowerPICC® Catheter	Similar when compared to predicate
ISO 10993-4: 2002/(R) 2013 & A1: 2006/ (R) 2013	Partial Thromboplastin Time (PTT) Predicate: PowerPICC® Catheter	Minimal activator (same as predicate)
ISO 10993-4: 2002/(R) 2013 & A1: 2006/ (R) 2013	Dog Thrombogenicity	Equivocal similar
AAMI/ANSI/ISO 10993-6:2007/(R)2014	Implantation	Non-irritant

Standard	Test Name	Result
ISO 10993-18 (Nelson Labs Report does not specify year.)	Extractable/Leachable Analysis	Summarized in project #MJ16357-BIO01
ISO 10993-17:2008	Subacute/Subchronic Toxicity, Genotoxicity, Chronic Toxicity and Carcinogencity	Evaluated in Toxicological Risk Assessment

Table 6: Vygon PICCs Biocompatibility Testing

VII. Conclusion

Through performance bench testing the subject devices have demonstrated that they are substantially equivalent to the predicate device, 5 Fr DL PowerPICC® Catheter, K051672.