May 21, 2018

Biowy Corporation
Andre Muller
Regulatory Affairs and Quality Assurance Manager
27031/27002 Vista Terrace
Lake Forest, California 92630

Re: K173956
Trade/Device Name: Biowy PICC Catheter
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: Class II
Product Code: LJS
Dated: April 16, 2018
Received: April 17, 2018

Dear Andre Muller:

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)*
K173956

Device Name
Biowy PICC Catheter

Indications for Use *(Describe)*
The Biowy PICC 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 4 French or larger catheter. The maximum recommended infusion rate is 5ml/sec for power injection of contrast media. The maximum pressure of power injectors used with the Biowy catheter may not exceed 300psi.

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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K173956 510(k) Summary

1. Submitter Information

Submitter Name:	Biowy Corporation
Address:	27031/27002 Vista Terrace Lake Forest, CA 92630 Telephone No. 1-(949) 305-8211 Fax Number: 1-(866) 506-5094
Primary Contact:	Andre von Muller RA/QA Manager Email: Avonmuller@biowy.com

Date of Preparation:	December 20, 2017

2. Device Information

Device Name	Biowy PICC Catheter
Trade Name:	Biowy PICC Catheter
Common/Usual Name:	Peripherally Inserted Central Catheter (PICC)
Regulation Number	21 CFR 880.5970
Regulation Name:	Percutaneous, implanted, long-term intravascular catheter
Regulatory Class:	II
Product Code:	LJS
Classification Panel:	General Hospital

3. Predicate Device:

Device Name:	5Fr DL PowerPICC® Catheter
Trade Name:	5Fr DL PowerPICC® Catheter
Premarket Notification:	K051672
Common/Usual Name	Peripherally Inserted Central Catheter (PICC)
Regulation Number	21 CFR 880.5970
Regulation Name:	Percutaneous, implanted, long-term intravascular catheter
Regulatory Class:	II
Product Code:	LJS
Classification Panel:	General Hospital

4. Device Description:

The Biowy PICC catheters are opened-ended radiopaque polyurethane catheters. The catheters are sterile and for single use. They are available in 4F single lumen with 55cm usable length and 5F dual lumen with 60cm usable length. The catheters have a reverse taper design. Catheter shaft is marked with depth indicators, with “0” indicated to serve as a reference for the catheter taper point. Catheters are provided sterile in radiology and nursing configurations for single use. Colorants were added to the catheter shaft and hub to differentiate components. The extension leg, junction and clamp were printed with markings to identify the catheter and to include information to facilitate proper use of the device.

5. Indications for Use

SUBJECT (K173956) Indications for Use	PREDICATE (K051672) Indications for Use
The Biowy PICC 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 4 French or larger catheter. The maximum recommended infusion rate is 5ml/sec for power injection of contrast media. The maximum pressure of power injectors used with the Biowy catheter may not exceed 300psi.	Identical to the FDA cleared 510(k) Indications for Use

6. Technological Comparison to Predicate

Element Comparison	Subject Device K173956	Predicate K051672
Mode of operation	Power Injection	Same
Size	5F and 4F	5F
Priming volume	4F (0.6ml), 5F (purple lumen 0.6ml, red lumen 0.6 ml)	0.57 ml
Length	60cm (5F), 55cm (4F)	55cm
Lumens	Dual (5F), Single (4F)	Dual
Distal end configuration	Oval (5F), Round (4F)	Oval
Intended anatomic location of distal end	lower 1/3 of Superior Vena Cava	Same
Proximal end configuration	Oval (5F), Round (4F) Reverse taper design	Oval (5F) Reverse taper design
Gravity water flow rate (ml/h)	695ml/h (5F) 434ml/h(4F)	578 ml/h
Power Injection 10x	Meet design requirement	N/A*
Burst pressure	267psi (5F), 278psi (4F)	223 psi
Biocompatibility (See list below)	Biocompatible	Same
Primary Device Materials	Polyurethane and barium sulfate	Same
Radiopacity	Detectable	Same

*Power Injection 10x: The subject device is additionally evaluated for worst-case scenario of 10x power injection. This difference of the power injection, flow rate and the burst pressure do not raise issues of safety and efficacy because the subject device is examined using the same ISO 10555-1 standard testing requirement as the predicate. The results fall within the limits allowed in the standard (ISO 10555-1).

The subject device (single lumen 4F and dual lumen 5F) are examined using the same testing requirements as the predicate. Therefore, the configuration difference does not raise issues of safety and efficacy.

The comparison above shows substantial equivalence of the subject device and the predicate.

7. Summary of Performance Tests

- *FDA Guidance on Premarket Notification [510(k)] Submission for Short-term and Long-term Intravascular Catheters 1995*
- *10555-1 Second Edition 2013-06-15 Intravascular Catheters -- Sterile and Single-Use Intravascular Catheters -- Part 1: General Requirements*
- *FDA Guidance for Industry 2016: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"*

Performance data gathered in design verification testing demonstrated that Biowy PICC catheter is substantially equivalent to the predicate 5 Fr DL PowerPICC catheter and the risk associated with use of the new device have been adequately mitigated.

The performance tests are listed below to demonstrate substantial equivalence of the subject device K173956 (4F SL and 5F DL), and applicable standards.

Test	Standards	Results
Critical Dimensions	ISO 9626:2015	Passed and met requirement
Priming Volume	Internal	Passed and met requirement
Tensile Force	ISO 10555-1:2014	Passed and met requirement
Elongation and Stiffness	Internal	Passed and met requirement
Flexural Fatigue	Internal	Passed and met requirement
Aspiration Flow/ Catheter collapse	Internal	Passed and met requirement
Air Leakage during Aspiration	ISO 10555-1:2014	Passed and met requirement
Gravity Flow	ISO 10555-1:2014	Passed and met requirement
Pump Flow	ISO 10555-1:2014	Passed and met requirement
Power Injection and Leak Testing	ISO 10555-1:2014	Passed and met requirement
Burst Pressure	ISO 10555-1:2014	Passed and met requirement
Power Injection/Burst Pressure	ISO 10555-1:2014	Passed and met requirement
Power Injection (10x)/ Burst Pressure	ISO 10555-1:2014	Passed and met requirement
Printing Marking	ISO 10555-3:2013	Passed and met requirement
6% Luer Taper	ISO 594-1:1986	Passed and met requirement
Luer	ISO 594-1:1986 ISO 594-2:1998	Passed and met requirement
Luer Color Orientation	Internal	Passed and met requirement
Radiopacity	ASTM F640-12	Passed and met requirement
List of Biocompatibility Tests:		
• Cytotoxicity	ISO 10993-5	Non-cytotoxic
• Sensitization	ISO 10993-10	Non-sensitizer
• Irritation	ISO 10993-10	Non-irritant
• Acute Systemic Injection	ISO 10993-11	Non-toxic
• Material Mediated Pyrogen	USP<151>	Non-pyrogenic
• LAL (Bacterial Endotoxins)	USP <85>, <161>	Passed and met requirements
• Hemolysis (extract)	ISO 10993-4	Non-hemolytic
• Hemolysis (direct)	ISO 10993-4	Non-hemolytic
• Complement Activation Predicate: PowerPICC® Catheter	ISO 10993-4	Similar when compared to predicate
• Partial Thromboplastin Time (PTT) Predicate: PowerPICC® Catheter	ISO 10993-4	Minimal activator (same as predicate)
• Dog Thrombogenicity	ISO 10993-4	Similar to control
• Implantation	ISO 10993-6	Non-irritant
• Subacute/sub Chronic Toxicity, • Genotoxicity, Chronic Toxicity, and Carcinogenicity	ISO 10993-17 ISO 10993-18	Passed and met requirement
EtO sterilization	ISO 11135: 2014	Met 10^{-6} SAL requirement
Clinical Evaluation	Internal	Passed
Accelerated Aging 1.5 year (4F SL, 5F DL) 3.0 year (4F SL, 5F DL)	ISO 11607-1:2006 ASTM F88/F88M-15 ISO 10555-1:2014	Passed and met requirement

Brief discussion of the non-clinical tests submitted for a determination of substantial equivalence:

Biowy has provided Performance Testing.
The Biowy PICC Catheters are designed, and made of the same polymer materials, use similar technological manufacturing methods, and have the same intended use as the predicate devices (PowerPICC Catheters).
Differences in technological characteristics (including flow rate, burst pressure, lumens, and the distal end configurations) of the device compared to the predicate do not raise different questions of safety and effectiveness.
Biowy has evaluated the differences using the same test requirements as the predicate device.
The subject devices are substantially equivalent to the predicate device in specifications comparison.

8. Conclusion

The Biowy PICC catheters (Model number PICC4SK and PICC5DK) has similar indications or use, technological characteristics and they meet all the predetermined performance acceptance criteria of the testing performed. Therefore, the devices are substantially equivalent to the predicate device the C.R. Bard 5 Fr DL PowerPICC® catheter, K051672.