April 30, 2020

Biowy Corporation
Arthur Lu
President
27031 Vista Terrace
Lake Forest, California 92630

Re: K192246
Trade/Device Name: Biowy PICC Catheter S Kit
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: Class II
Product Code: LJS
Dated: March 27, 2020
Received: March 31, 2020

Dear Arthur Lu:

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 Tina Kiang, Ph.D.
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)*
K192246

Device Name

Biowy PICC Catheter S Kit

Indications for Use *(Describe)*

The Biowy PICC catheter S Kit 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. The catheter is available in a kit configuration.

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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Biowy Corporation

Biowy PICC Catheter S Kit

Traditional 510(k)

K192246 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:	Arthur Lu Email: alu@biowy.com
Date of Preparation:	April 28,2020

2. Device Information

Device Name:	Biowy PICC Catheter S Kit
Trade Name:	Biowy PICC Catheter S Kit
Model numbers:	PICC4SK-S and PICC5DK-S
Common/Usual Name:	Peripherally Inserted Central Catheter (PICC)
Regulation Description:	Percutaneous, implanted, long-term intravascular catheter
Regulation Number:	21 CFR 880.5970
Device Class	II
Product Code:	LJS
Classification Panel:	General Hospital

3. Predicate Devices:

Predicate Name:	Biowy PICC Catheter
Trade Name:	Biowy PICC Catheter
Common/Usual Name:	Peripherally Inserted Central Catheter (PICC)
Regulation Description:	Percutaneous, implanted, long-term intravascular catheter
Regulation Number	21 CFR 880.5970
Product Code:	LJS
Device Class:	II
Premarket Notification:	K173956
Manufacturer	Biowy Corporation

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. The Catheter is provided in a kit with multiple components that includes a stylet, torque adapter and T-lock to facilitate catheter insertion and flushing which are subject to this submission. The stylet has a torque adapter at the end to facilitate handling and withdrawal of the stylet. The catheter and other components in the kit are unchanged from the predicate device.

5. Indications for Use

Primary predicate K173956	Subject device K192246
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.	The Biowy PICC Catheter S Kit 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. The catheter is available in a kit configuration.

6. Technological Comparison to Predicate

Element Comparison	Predicate K173956	Subject Device K192246
Device Name	**Biowy PICC Catheter**	**Biowy PICC Catheter S Kit**
Regulatory Class	**II**	**II**
Classification	**21 CFR 880.5970**	**21 CFR 880.5970**
Product Code	**LJS**	**LJS**
Catheter Needle Guidewire Microintroducer Syringe Needleless valve/cap Drape Tray Wrap Measure tape	**4Fr x 55cm Single Lumen** **5Fr x 60cm Double lumen**	**Unchanged from the predicate K173956**
Additional Components in Kit	Not provided	T-Lock (Tuohy Burst Adapter)
		Stylet (stainless steel)
		Torque Adapter (cleared in K922536)
Biocompatibility	10993-1	10993-1
Sterilization	Ethylene Oxide	Same

The subject device (single lumen 4F and dual lumen 5F) are examined using the same testing requirements as the predicate. A stylet is added in the catheter to support and facilitate catheter insertion. A T-lock is provided to lock the stylet with the catheter and to facilitate flushing. The stylet has a torque adapter at the end to facilitate handling and withdrawal of the stylet. Biocompatibility and performance of the new features are evaluated and meet the requirements for their intended use. The new feature does not add a new question of safety and effectiveness.

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

7. Summary of Non-Clinical Testing

- *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 S Kit is substantially equivalent to the predicate Biowy PICC 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. A risk assessment in conformance to ISO 14971 was performed.

Test	Standards	Results
Biocompatibility	ISO 10993-1	Passed / met requirements
Sterility Assurance Level (SAL)	ISO 11135-1:2014	10^{-6}
Particulates	USP <788>	Passed / met requirements
Stylet Inspections and Lock Test	Internal	Passed / met requirements
Catheter Burst test after stylet insertion	ISO 10555-1:2013	Passed / met requirements
Stylet Adapter Tensile Test	ISO 10555-1:2013	Passed / met requirements
Stylet-Adapter Separation Force	ISO 10555-1:2013	Passed / met requirements
Stylet performance	ISO 10555-1:2013 Internal	Passed / met requirements
Stylet -Materials	ASTM 138-13	Passed

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

The Biowy PICC catheter used in the subject device is identical to that in the predicate device Biowy PICC Catheter. The catheter was designed, made of the same polymer materials, use the same technological manufacturing methods, and have the same intended use as the predicate devices.
Biowy has conducted bench performance testing. There are no differences in technological characteristics (including flow rate, burst pressure, lumens, and the distal end configurations) of catheter compared to the predicate.
The only difference between the subject device and the predicate device is that the subject has three additional accessories used for catheter placement. Biocompatibility and performance tests of the additional components including stylet insertion, catheter burst, tensile, flexibility, and torque strength are evaluated and meet the requirements for their intended use. Therefore, the subject devices are

substantially equivalent to the predicate device. The indications for use is similar. The indications for use for the subject device states that it is available in a kit configuration.

8. Conclusion

The addition of the Stylet, T-Lock, and Torque adapter in the Biowy PICC Catheter S Kits (Model number PICC4SK-S and PICC5DK-S) met all the predetermined performance acceptance criteria of the testing performed. The addition of these components does not change the intended use of the device and, based on FDA's decision tree, is considered substantially equivalent to the predicate device: the Biowy PICC catheter, K173956.