September 30, 2020

Big Blue Biotech, Inc.
℅ Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite 510k
Saint Paul, MN 55114

Re: K202566
Trade/Device Name: Wiygul Catheter
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: EZD
Dated: September 3, 2020
Received: September 4, 2020

Dear Prithul Bom:

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,

Sharon M. Andrews
Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K202566

Device Name
Wiygul Catheter

Indications for Use *(Describe)*
The Wiygul Catheter is intended for use in the neonate and infant subpopulations of pediatric patients to sample urine. This device is removed after a urine sample is collected. This is not an indwelling 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.

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.

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"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."

510(k) Summary

The following information is provided in accordance with 21 CFR 807.92, for the Premarket 510(k) Summary:

SUBMITTER INFORMATION

Company Name:	Big Blue Biotech, Inc.
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Date Prepared:	September 18, 2020

DEVICE INFORMATION:

Trade Name:	Wiygul Catheter
Common Name:	Pediatric Urinary Sampling Catheter
Regulatory Class:	Class II
Product Code:	EZD
Product Code Name:	Catheter, Straight
Classification Name:	Urological Catheter and Accessories
Regulation Number:	21 CFR 876.5130

PREDICATE DEVICE INFORMATON:

Trade Name:	NeoMed Urinary Catheter
Common Name:	Urological Catheter and Accessories
Subject to design-related recall:	No
510(k) Number:	K072997
Decision Date:	December 19, 2007

DEVICE DESCRIPTION:

The Wiygul Catheter intended for use in neonatal and pediatric patients to sample urine. This device is removed after a urine sample is collected. This is not an indwelling catheter. The Wiygul Catheter is comprised of a two-layer design, including an inner sampling catheter and protective outer sheath to minimize contamination of the eyelets. The tip will be atraumatic. The handle of the device will utilize a slider to facilitate the retraction of the outer sheath once inserted into the bladder to expose eyelets for sampling. This catheter is a6Fr catheter with a working length of 300mm +/- 5mm. Material composition of the catheter is provided in in Table 5-1 below.

The Wiygul Catheter is provided in a box containing the main device (sampling catheter), a cleared syringe and Instructions for Use.

The mechanism of action will be mechanical for pulling back the outer sheathe and negative pressure from the attached syringe to withdraw a urine sample.

Table 5-1: Material Composition

Component	Surface Area (in^2)	Percent Surface Are	Volume (in^3)	Percent Volume	Material	Color
Outer Sheath	5.429	36%	0.0216	12%	Dow 690 Health+ LDPE, 9% Elvax 660, 0.2% Crodamide	2925c
Sampling Catheter	3.815	25%	0.0192	10%	Dow 690 Health+ LDPE, 9% Elvax 660, 0.2% Crodamide	286c
Distal Handle	2.600	17%	0.0729	39%	Bayblend T85 XF-000000	UN0005 3%
roximal Luer Handl	1.683	11%	0.0411	22%	Bayblend T85 XF-000000	UN0005 3%
Slider Handle	1.498	10%	0.0317	17%	Cycoloy C1200HF-1000	286c

INTENDED USE OF Wiygul Catheter

The Wiygul Catheter is intended for use in the neonate and infant subpopulations of pediatric patients to sample urine. This device is removed after a urine sample is collected. This is not an indwelling catheter.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Attributes	Subject device Wiygul Catheter	Predicate device NeoMed Urinary Catheter	Remarks
510k Number	K2020566	K072997	N/A
Trade Name	Wiygul Catheter	NeoMed Urinary Catheter	N/A
Classification Name	Urological Catheter and Accessories	Urological Catheter and Accessories, Urethral Catheter	The predicate has one additional procode.
Device Classification	Class II	Class II	Same
Product Code	EZD	EZD and GBM	The predicate has one additional procode.
Indications for Use	Urine Sampling	Urine Sampling and/or bladder drainage	Similar. The subject device is intended to collect the urine sample only, and it is not intended for bladder drainage.
Intended Use	This Wiygul Catheter is intended for use in neonate and infant subpopulations of pediatric patients to sample urine. This device is removed after a urine sample is collected. This is not an indwelling catheter.	This product is intended for use in neonatal and pediatric patients to sample urine and/or facilitate urinary drainage. This catheter is NOT a Foley (balloon) type catheter. This catheter is intended for temporary use and will be in contact with the patient for less than 30 days.	Similar. The subject device is intended to collect the urine sample only, and it is not intended for bladder drainage.
Device Description	The Wiygul Catheter is comprised of a two-layer design, including an inner sampling catheter and protective outer sheath. The tip is atraumatic. The handle of the device will utilize a slider to facilitate the retraction of the outer sheath once inserted to expose eyelets for sampling.	The NeoMed Urinary Catheter is a silicone single lumen catheter that is used to drain urine. The device consists of the following components: a single lumen urinary catheter, a hub, and a luer lock connector. It is available with either an orange radiopaque stripe or a natural white stripe (supplied from the barium sulfate loaded in the catheter)	Similar Both devices have sampling catheter, and luer lock connector to connect the syringe and draw the urine sample. The subject device has an additional outer sheath. The outer sheathe of the subject device has laser engraved

Attributes	Subject device Wiygul Catheter	Predicate device NeoMed Urinary Catheter	Remarks
			markings.
Target Population	Neonatal and Pediatric patients	Neonatal and Pediatric patients	Same
Materials	PC/ABS and LDPE/Elvax/Crodamide blend	Silicone	Different. The biocompatibility, performance test and simulated use data demonstrates that the difference in material of the subject device compared to its predicate does not raise any safety and effectiveness concerns.
Biocompatibility	Passed ISO 10993 Cytotoxicity, Irritation, and Sensitization testing	"The NeoMed Urinary Catheter materials that come in direct contact with the patient have a long history of use in catheter and urethral catheter manufacture and are biocompatible."	Similar. The biocompatibility test results of the subject device demonstrate that the subject device is biocompatible.
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Same
Performance Data	Functional test results demonstrate that the Wiygul Catheter performs its intended use of urine sampling and is equivalent to the predicate device.	Functional test results demonstrate that the NeoMed Urinary catheter performs its intended use of urine drainage and is equivalent to the predicate device.	Similar.
Anatomical Sites	Urethral	Urethral	Same

PERFORMANCE DATA

Summary of Performance Testing

The following non-clinical performance data are provided in support of the substantial equivalence determination:

- Pouch Sealing
- Visual Inspection
- Dimensional Inspection
- Simulated Use Testing
- Flow Rate Testing
- Kink Testing
- Tensile Testing
- Luer Testing per BBB ISO 80369-7
- Package Distribution Simulation Testing per ASTM 4169-16
- Package Integrity Visual Inspection
- Package Integrity Bubble Leak Testing per ASTM F2096-11
- Package Strength Testing per ASTM F88/F88M-15
- Bend Radius Test
- KY Jelly Compatibility Test

All tests met the pre-determined acceptance criteria.

Conclusion:

The subject device has the same indented use and similar technological characteristics to the currently-marketed predicate device. The subject device is substantially equivalent to the currently-marketed predicate devices. The non-clinical performance testing conducted on the product demonstrates the Wiygul Catheter is as safe and effective as the predicate device for it's intended use.