October 9, 2020

Bioteque Corporation
Stella Hsu
RA Specialist
5F-6, No. 23, Sec. 1, Chang'an E. Rd., Zhongshan Dist.
Taipei City, 10441
TAIWAN

Re: K200103
Trade/Device Name: BIOTEQ Drainage Catheter Set (One Step Type)
Regulation Number: 21 CFR 876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: FGE, GBO
Dated: September 4, 2020
Received: September 8, 2020

Dear Stella Hsu:

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,

Glenn B. Bell, Ph.D.
Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K200103

Device Name
BIOTEQ Drainage Catheter Set (One Step Type)
Model Name: BT-PD1-series

Indications for Use *(Describe)*

The BIOTEQ Drainage Catheter Set (One Step Type) is designed for percutaneous drainage of abscess fluid, cyst, gall bladders, nephrostomy, urinary, and others fluids.

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

5.1 Type of Submission: Traditional

5.2 Date of Summary: January 16, 2020

5.3 Submitter:

Address:	5F-6, No. 23, Sec. 1, Chang'an E. Rd., Zhongshan Dist. Taipei City 10441, Taiwan
Phone:	+886-2-2571-0269
Fax:	+886-2-2536-1967
Contact:	William Lee (General Manager)

5.4 Identification of the Device:

Proprietary/Trade name:	BIOTEQ Drainage Catheter Set (One Step Type) Model Name: BT-PD1-series
Classification Product Code:	FGE
Subsequent Product Code:	GBO
Regulation Number:	876.5010; 878.4200
Regulation Description:	Biliary catheter and accessories; Introduction/drainage catheter and accessories.
Review Panel:	Gastroenterology/Urology; General & Plastic Surgery
Device Class:	II
Basis for the Submission:	New Device

5.5 Identification of the Predicate Device I:

Predicate Device Name:	General Purpose Drainage Catheter
Manufacturer:	UreSil, LLC
Classification Product Code:	FGE
Subsequent Product Code:	GBO, GBX, LJE
Regulation number:	876.5010
Device Class:	II

510(k) Number: K053245

5.6 Identification of the Predicate Device II:

Predicate Device Name:	BIOTEQ® Pigtail Drainage Catheter Set (One Step Type)
Manufacturer:	BIOTEQUE CORPORATION
Classification Product Code:	LHI
Subsequent Product Code:	NEP
Regulation number:	880.5440
Device Class:	II
510(k) Number:	K033862

5.7 Intended Use

The BIOTEQ Drainage Catheter Set (One Step Type) is designed for percutaneous drainage of abscess fluid, cyst, gall bladders, nephrostomy, urinary, and others fluids.

5.8 Device Description

The BIOTEQ Drainage Catheter Set (One Step Type), BT-PD1-series percutaneous drainage catheter with hydrophilic coating, is a percutaneous drainage catheter used for drainage of abscess and fluid collections. The catheter is made from a soft, biocompatible plastic, a material that is radiopaque for X-rays. The distal end of catheter contains a “J”, a pigtail or close loop and drainage holes.

The operator can use different drainage sets according to the type of accumulated fluid and place of accumulation. These sets are classified according to the catheter size (5F~16F pertaining to various fluid viscosity) and according to the position of the accumulation. The operator can choose either Direct Access Technique or Seldinger Technique to provide access.

5.9 Non-clinical Testing

A series of safety and performance tests were conducted on the subject device,

BIOTEQ Drainage Catheter Set (One Step Type).

- Sterilization Validation
- Shelf-life
- Biocompatibility
- Performance

All the test results demonstrate BIOTEQ Drainage Catheter Set (One Step Type) meets the requirements of its pre-defined acceptance criteria and intended use, and is substantially equivalent to the predicate devices.

5.10 Clinical Testing

No clinical test data was used to support the decision of substantial equivalence.

5.11 Substantial Equivalence Determination

Equivalence, same and difference between the subject and predicate devices are cited as below.

Item	Subject device	Predicate device I	Predicate device II	Substantial equivalence determination
Proprietary Name	BIOTEQ Drainage Catheter Set (One Step Type)	General Purpose Drainage Catheter	BIOTEQ® Pigtail Drainage Catheter Set (One Step Type)	
510(k) No.	(to be assigned)	K053245	K033862	
Intended Use	The BIOTEQ Drainage Catheter Set (One Step Type) is designed for percutaneous drainage of abscess fluid, cyst, gall bladders, nephrostomy, urinary, and others fluids.	For percutaneous drainage of abscesses, nephrostomy and other fluids.	BIOTEQ® Pigtail Drainage Catheter Set (One Step Type) is intended to be used for percutaneous drainage of abscesses, cysts, gall bladders, nephrostomies and other fluids.	***Equivalent*** All the devices are used for percutaneous drainage in gastroenterology and urology.
Type of use	Prescription Use	Prescription Use	Prescription Use	***Same***

Catheter Shaft Material	TPU	TPU	TPU	***Same***
Distal configuration	String Locking Pigtail, Non-String Locking Pigtail	String Locking Pigtail, Non-String Locking Pigtail	String Locking Pigtail, Non-String Locking Pigtail	***Same***
Distal shape	Pigtail, Closed-Pigtail, Mini-Pigtail, Mini-closed Pigtail, J shape	Pigtail, Closed-Pigtail, Mini-Pigtail, J shape	Pigtail	***Equivalent*** All the devices have pigtail, closed, mini, and J shape.
Distal Hydrophilic Coating	Yes	Yes	Yes	***Same***
Shaft Depth Printing Markers	Yes	Yes	Yes	***Same***
Proximal Hub Assembly	Hub (for String Lock Pigtail), F.L.L. Adapter	Hub (for String Lock Pigtail), F.L.L. Adapter	Screw Cap, F.L.L Adapter	***Same*** *as predicate I*
Size	5 Fr (Non-String Lock), 6, 7, 8, 10, 12, 14, 16 Fr	6, 8, 10, 12, 14, 16 Fr	7, 8, 9, 10, 12, 14 Fr	Different but do not raise new issues of SE.
Useable Length	20, 25, 30, 35, 40, 45, 50 cm	12, 18, 19, 20, 25, 28, 40, 41, 50 cm	20, 30, 40 cm	Different but do not raise new issues of SE.
Included Insert Accessory	• Trocar Needle (Metal Stiffening Cannula) • Trcoar Stylet • Flexible (plastic) Stiffening Cannula • Wire cap (for string Lock Pigtail) • Suture Wire • Curve Straightener • Radiopaque band	• Trocar Needle (Metal Stiffening Cannula) • Trcoar Stylet (Trocar) • Flexible Cannula • Wire-Ring • Suture Wire • Radiopaque marker	• Trocar Needle (Metal Stiffening Cannula) • Trcoar Stylet • Wire cap (for string Lock Pigtail) • Suture Wire • Curve Straightener	Different but do not raise new issues of SE.

Packaging	Tyvek/Mylar (PET/LDPE) pouch	Tyvek/Mylar pouch	Tyvek/Mylar (PET/LDPE) pouch	***Same** as predicate II*
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide	***Same***

5.12 Similarity and Difference

The BIOTEQ Drainage Catheter Set (One Step Type) has been compared with "General Purpose Drainage Catheter" and "BIOTEQ® Pigtail Drainage Catheter Set (One Step Type)". The subject device has same intended use, principle of operation and similar technological characteristics as the predicate devices. The subject device has undergone safety and performance tests, and the results complied with the test requests. Although there are some different specifications between these devices, the performance test has been completed to demonstrate that the differences between these parameters would not impact the safety and effectiveness of the subject device. Therefore, the difference between the subject device and the predicate devices did not raise any new issue of substantial equivalence. The subject device is substantially equivalent to the predicate devices in intended use, design and performance claims.

5.13 Conclusion

After analyzing non-clinical laboratory studies and safety testing data, it can be concluded that the BIOTEQ Drainage Catheter Set (One Step Type) is substantially equivalent to the predicate devices.