April 13, 2022

Bioteque Corporation
Stella Hsu
RA Specialist
5F-6, No. 23, Sec. 1, Chang'an E. Rd., Zhongshan Dist.
Taipei City, 104
Taiwan

Re: K210419
Trade/Device Name: BIOTEQ Drainage Catheter Set (Seldinger Type)
Model Name: BT-PDS-series
Regulation Number: 21 CFR§ 876.5010
Regulation Name: Biliary Catheter and Accessories
Regulatory Class: II
Product Code: FGE, LJE, GBO
Dated: March 15, 2022
Received: March 16, 2022

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,

Je Hi An, Ph.D.
Assistant 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210419

Device Name
BIOTEQ Drainage Catheter Set (Seldinger Type)
Model Name: BT-PDS-series

Indications for Use *(Describe)*
The BIOTEQ Drainage Catheter Set (Seldinger Type) is designed for percutaneous drainage of abscess fluid, cyst, gall bladders nephrostomy, urinary and other 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: March 31, 2022

5.3 Submitter:

Address:	BIOTEQUE CORPORATION 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:	Stella Hsu

5.4 Identification of the Device:

Proprietary/T de name:	BIOTEQ Drainage Catheter Set (Seldinger Type) Model Name: BT-PDS-series
Classification Product Code:	FGE
Subsequent Product Code:	LJE, GBO
Regulation Number:	876.5010
Regulation Description:	Biliary 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:

Predicate Devi ce Name:	BIOTEQ Drainage Catheter Set (One Step Type) Model Name: BT-PD1-series
Manufacturer	BIOTEQUE CORPORATION
Classification Product Code:	FGE
Subsequent Product Code:	LJE, GBO
Regulation number	876.5010
Device Class:	II
510(k) Number:	K200103

5.6 Device Description

The BIOTEQ Drainage Catheter Set (Seldinger Type), BT-PDS-series percutaneous drainage catheter with hydrophilic coating, are percutaneous drainage catheters 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 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 (8F~14F pertaining to various fluid viscosity) and according to the position of the accumulation. The operator should use Seldinger Technique to provide access.

5.7 Indications for Use

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

5.8 Comparison of Technological Characteristics with Predicate Device

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

Item	Subject device	Predicate device	Substantial equivalence determination
Proprietary Name	BIOTEQ Drainage Catheter Set (Seldinger Type)	BIOTEQ Drainage Catheter Set (One Step Type)	
510(k) No.	K210419	K200103	
Intended Use	The BIOTEQ Drainage Catheter Set (Seldinger Type) is designed for percutaneous drainage of abscess fluid, cyst, gall bladders nephrostomy, urinary and other fluids.	The BIOTEQ Drainage Catheter Set (One Step Type) is designed for percutaneous drainage of abscess fluid, cyst, gall bladders, nephrostomy, urinary, and others fluids.	***Equivalent*** Both the devices are used for percutaneous drainage in Gastroenterology and urology.
Type of Use	Prescription Use	Prescription Use	***Same***
Intended User	Adults and recommending clinician should choose an appropriate catheter size for pediatric use.	Adults and recommending clinician should choose an appropriate catheter size for pediatric use.	***Same***

BIOTEQUE CORPORATION
BIOTEQ Drainage Catheter Set (Seldinger Type)

Traditional 510(k), K210419
Summary

Item	Subject device	Predicate device	Substantial equivalence determination
Proprietary Name	BIOTEQ Drainage Catheter Set (Seldinger Type)	BIOTEQ Drainage Catheter Set (One Step Type)	
510(k) No.	K210419	K200103	
Catheter Shaft Material	TPU	TPU	***Same***
Distal Configuration	String Locking Pigtail, Non-String Locking Pigtail	String Locking Pigtail, Non-String Locking Pigtail	***Same***
Distal Shape	Pigtail, Closed-Pigtail	Pigtail, Closed-Pigtail, Mini-Pigtail, Mini-closed Pigtail, J shape	***Equivalent*** Both the devices have pigtail and closed shape.
Distal Hydrophilic Coating	Yes	Yes	***Same***
Shaft Depth Printing Markers	Yes	Yes	***Same***
Proximal Hub Assembly	Hub (for String Lock Pigtail), F.L.L. Adapter	Hub (for String Lock Pigtail), F.L.L. Adapter	***Same***
Size	8, 10, 12, 14 Fr	5 Fr (Non-String Lock), 6, 7, 8, 10, 12, 14, 16 Fr	***Equivalent*** The size range of subject device is equivalent to the predicate device.
Useable Length	40, 45, 50 cm	20, 25, 30, 35, 40, 45, 50 cm	***Equivalent*** The length range of subject device is equivalent to the predicate device.
Included Insert Accessory	• Metal Stiffening Cannula • Flexible (plastic) Stiffening Cannula • Wire cap • Suture Wire • Curve Straightener	• Trocar Needle • Trocar Stylet • Flexible (plastic) Stiffening Cannula • Wire cap • Suture Wire	***Equivalent*** The accessories of subject device equivalent to the predicate device.

Item	Subject device	Predicate device	Substantial equivalence determination
Proprietary Name	BIOTEQ Drainage Catheter Set (Seldinger Type)	BIOTEQ Drainage Catheter Set (One Step Type)	
510(k) No.	K210419	K200103	
	• Radiopaque band	• Curve Straightener • Radiopaque band	
Packaging	Tyvek/Mylar (PET/LDPE) pouch	Tyvek/Mylar (PET/LDPE) pouch	***Same***
Sterilization Method	Ethylene Oxide	Ethylene Oxide	***Same***

5.9 Similarity and Difference

The BIOTEQ Drainage Catheter Set (Seldinger Type) has been compared with "BIOTEQ Drainage Catheter Set (One Step Type)". The subject device has the same intended use, and similar principle of operation and technological characteristics as the predicate device. 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 do not raise different types of safety and effectiveness questions. The subject device is substantially equivalent to the predicate device in intended use, design and performance claims.

5.10 Performance Data - Non-clinical Testing

The following performance data were provided in support of the substantial equivalence determination.

- Sterilization Validation
  The ethylene oxide (EO) sterilization and related validation testing were conducted in accordance and complied with ISO 11135, ISO 10993-7, ISO 11737-1, ISO 11737-2, USP <85>, and ASTM F1140/F1140M.
- Shelf-life
  The shelf-life testing were conducted in accordance and complied with ASTM F1980, ASTM F1929, and ASTM F1140/F1140M.
- Biocompatibility
  The biocompatibility evaluation was conducted in accordance and complied with the FDA

Guidance "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"" and International Standard ISO 10993-1:2018, Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process as recognized by FDA. The endpoint testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Pyrogenicity
- Subchronic Systemic Toxicity
- Genotoxicity
- Implantation

- Performance

  The performance testing were conducted in accordance and complied with EN 1617, ISO 20697, ASTM F640, EN 1618, ISO 594-2, ISO 80369-7, ISO 11070, ASTM F1828 and ISO 7864.

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

5.11 Performance Data - Clinical Testing

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

5.12 Conclusion

The data demonstrate the subject device is as safe and effective as the primary predicate device. The data support the safety and performance of the subject device, and demonstrate that the subject device should perform as intended in the specified use conditions. The data demonstrates that the BIOTEQ Drainage Catheter Set (Seldinger Type) performs comparably to the predicate device that is currently marketed for the same intended use.