December 22, 2025

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

Re: K251019
Trade/Device Name: BIOTEQ Drainage Catheter Set: BT-PD1-SERIES and BT-PDS-SERIES
Regulation Number: 21 CFR 876.5010
Regulation Name: Biliary Catheter And Accessories
Regulatory Class: Class II
Product Code: FGE, LJE, GBO
Dated: November 20, 2025
Received: November 20, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

ANTHONY LEE -S

Anthony Lee, Ph.D., MBA
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251019

Device Name
BIOTEQ Drainage Catheter Set: BT-PD1-SERIES-G and BT-PDS-SERIES-G

Indications for Use *(Describe)*
The catheter 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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"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."

Bioteque Corporation
BIOTEQ Drainage Catheter Set

510(k) Summary

1. **Type of submission:** Traditional
   Date of Summary: December 19, 2025

2. **Submitter:** Bioteque Corporation

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Phone	+886-2-2571-0269 ext. 1348
Fax	+886-2-2536-1967
Contact	Stella Hsu (stellahsu@bioteq.com.tw)

3. **Identification of the Device:**
   Device Name: BIOTEQ Drainage Catheter Set
   Classification Product Code: FGE
   Subsequent Product Code: LJE, GBO
   Regulation Number: 876.5010
   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

4. **Identification of the Predicate Device I:**
   Predicate Device Name: BIOTEQ Drainage Catheter Set (Seldinger Type) Model name: BT-PDS-series
   Manufacturer: Bioteque Corporation
   Classification Product Code: FGE
   Subsequent Product Code: LJE, GBO
   Regulation number: 876.5010
   Device Class: II
   510(k) number: K210419

5. **Identification of the Predicate Device II:**
   Predicate Device 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

6. Device Description

The BT-PD1-SERIES-G / BT-PD1-SERIES(MN)-G / BT-PD1-SERIES-G(+FSC) / BT-PDS-SERIES-G / BT-PDS-SERIES(MN)-G / BT-PDS-SERIES(B)-RB-G 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 pigtail or mini-pigtail close loop and drainage holes.

7. Indications for Use

The catheter is designed for percutaneous drainage of abscess fluid, cyst, gall bladders, nephrostomy, urinary, and others fluids.

8. Performance Data - Non-clinical Testing

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

(1) 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, and EN 556-1.

(2) Shelf-life

The shelf-life testing was conducted and complied with ISO 20697, ISO 80369-7, 80369-20, ASTM F1140/F1140M, ISO11070, ISO9626, ISO 2859-1.

(3) Biocompatibility

The biocompatibility evaluation was conducted, and the endpoint testing included the following tests:

- In vitro Cytotoxicity test
- Skin Sensitization Study in Guinea Pigs
- Intracutaneous Irritation Study in White Rabbits
- Acute Systemic Toxicity Study in Mice

- Pyrogen test in white rabbit
- A Dual Route sub chronic systemic toxicity study in rats
- Salmonella reverse mutation test
- In vitro mammalian chromosomal aberration test
- Rodent Micronucleus Test in Peripheral Blood
- Muscle Implantation study in white rabbits

(4) Performance

The performance testing was conducted and complied with ISO 20697, ISO 80369-7, ISO 80369-20.

9. Performance Data - Clinical Testing

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

10. Substantial equivalence comparison

BIOTEQ Drainage Catheter Set submitted in 510(k) files is substantially equivalent in intended use, safety and performance to the FDA cleared BIOTEQ Drainage Catheter Set (Seldinger Type) (K210419) and BIOTEQ Drainage Catheter Set (One Step Type) (K200103). Differences between the devices cited in this section do not raise any new issue of substantial equivalence.

Bioteque Corporation
BIOTEQ Drainage Catheter Set

Item	Subject device	Predicate device	Substantial equivalence determination
Proprietary name	BIOTEQ Drainage Catheter Set	BIOTEQ Drainage Catheter Set	
Series	BT-PDS-series-G	BT-PDS-series	-
510(k) No.	K251019	K210419	-
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 (Seldinger Type) is designed for percutaneous drainage of abscess fluid, cyst, gall bladders nephrostomy, urinary and other fluids.	Equivalent Both the devices are used for percutaneous drainage in gastroenterology and urology.
Type of Use	Prescription Use	Prescription Use	Same
Intended patient population	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
Catheter Shaft Material	TPU	TPU	Same
Coating Material	Hydromer AQUA 65JL	Hydromer AQUA 65JL	Same
Catheter color	**Green**	**Blue**	**Different**
Distal Configuration	String Locking Pigtail, Non-String Locking Pigtail	String Locking Pigtail, Non-String Locking Pigtail	Same

Item	Subject device	Predicate device	Substantial equivalence determination
Proprietary name	BIOTEQ Drainage Catheter Set	BIOTEQ Drainage Catheter Set	
Distal Shape	Pigtail, Mini-closed Pigtail	Pigtail, Closed-Pigtail	Equivalent Both the devices have pigtail 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	5 Fr (Non-String Lock), 6, 7, 8, 10, 12, 14, 16 Fr	8, 10, 12, 14 Fr	Different but do not raise new issues of SE
Usable Length	20, 25, 30, 35, 40, 45, 50 cm	40, 45, 50 cm	Different but do not raise new issues of SE
Included Insert Accessory	Metal Stiffening Cannula Flexible (plastic) Stiffening Cannula Wire cap, Suture Wire, Curve Straightener, Radiopaque band	Metal Stiffening Cannula Flexible (plastic) Stiffening Cannula Wire cap, Suture Wire, Curve Straightener, Radiopaque band	Equivalent The accessory of subject device is equivalent to the predicate device
Packaging	Tyvek/Mylar (PET/LDPE) pouch	Tyvek/Mylar (PET/LDPE) pouch	Same

Item	Subject device	Predicate device	Substantial equivalence determination
Proprietary name	BIOTEQ Drainage Catheter Set	BIOTEQ Drainage Catheter Set	
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Same

Item	Subject device	Predicate device	Substantial equivalence determination
Proprietary name	BIOTEQ Drainage Catheter Set (One step Type)	BIOTEQ Drainage Catheter Set (One Step Type)	
Series	BT-PD1-series-G	BT-PD1-series	-
510(k) No.	K251019	K200103	-
Intended Use	The BIOTEQ Drainage Catheter Set (One step 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 other fluids.	Equivalent Both the devices are used for percutaneous drainage in gastroenterology and urology.
Type of Use	Prescription Use	Prescription Use	Same
Intended patient population	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
Catheter Shaft Material	TPU	TPU	Same
Coating Material	Hydromer AQUA 65JL	Hydromer AQUA 65JL	Same
Catheter color	**Green**	**Blue**	**Different**
Distal Configuration	String Locking Pigtail, Non-String Locking Pigtail	String Locking Pigtail, Non-String Locking Pigtail	Same

Item	Subject device	Predicate device	Substantial equivalence determination
Proprietary name	BIOTEQ Drainage Catheter Set (One step Type)	BIOTEQ Drainage Catheter Set (One Step Type)	
Distal Shape	Pigtail, Mini-closed Pigtail	Pigtail, Closed-Pigtail, Mini-Pigtail, Mini-closed Pigtail, J shape	Equivalent All the devices have pigtail and mini-closed pigtail 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	5 Fr (Non-String Lock), 6, 7, 8, 10, 12, 14, 16 Fr	5 Fr (Non-String Lock), 6, 7, 8, 10, 12, 14, 16 Fr	Same
Useable Length	20, 25, 30, 35, 40, 45, 50 cm	20, 25, 30, 35, 40, 45, 50 cm	Same
Included Insert Accessory	Trocar needle, Trocar stylet Flexible (plastic) Stiffening Cannula Wire cap, Suture Wire, Curve Straightener	Trocar needle, Trocar stylet Flexible (plastic) Stiffening Cannula Wire cap, Suture Wire, Curve Straightener	Same
Packaging	Tyvek/Mylar (PET/LDPE) pouch	Tyvek/Mylar (PET/LDPE) pouch	Same

Item	Subject device	Predicate device	Substantial equivalence determination
Proprietary name	BIOTEQ Drainage Catheter Set (One step Type)	BIOTEQ Drainage Catheter Set (One Step Type)	
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Same

11. Conclusion

The data supports the safety and performance of the subject device and demonstrates that the subject device is substantially equivalent to the predicate device.