DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 22, 2016

Bioteque Corp.
Stella Hsu
5F-6, No. 23, Sec. 1
Chang-an E. Road
Taipei 104, Taiwan

Re: K150932
Trade/Device Name: Sheath Introducer
Regulation Number: 21 CFR 870.1310
Regulation Name: Vessel Dilator For Percutaneous Catheterization
Regulatory Class: Class II
Product Code: DRE
Dated: May 30, 2016
Received: June 2, 2016

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Brian D. Pullin -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150932

Device Name
Sheath Introducer

Indications for Use *(Describe)*
The Bioteq Sheath Introducer is intended to provide access and facilitate the percutaneous introduction of various devices into veins and/or arteries while maintaining hemostasis for a variety of diagnostic and therapeutic procedures.

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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510(k) Summary

5.1 Type of Submission: Traditional

5.2 Date of Summary: 07/15/2016

5.3 Submitter:

Address: 5F-6, No.23 Sec.1, Chang-An E. Rd., Taipei 104, Taiwan
Phone: +886-2-2571-0269
Fax: +886-2-2536-1967
Correspondent: Stella Hsu
Registration number: 9615118

5.4 Identification of the Device:

Proprietary/Trade name: Sheath Introducer
Classification Name: Vessel Dilator for Percutaneous Catheterization
Device Classification: II
Regulation Number: 870.1310
Panel: Cardiovascular
Product Code: DRE

5.5 Identification of the Predicate Device:

Predicate Device Name: Merit Prelude™ Sheath Introducer
Manufacturer: Merit Medical Systems, Inc.
Regulation Number: 870.1310
Panel: Cardiovascular
Product Code: DRE
510(k) Number: K050962

5.6 Intended Use and Indications for Use of the subject device.

The Bioteq Sheath Introducer is intended to provide access and facilitate the percutaneous introduction of various devices into veins and/or arteries while maintaining hemostasis for a variety of diagnostic and therapeutic procedures.

5.7 Device Description

Bioteq Sheath Introducer consists of a sheath introducer with side port extension and stopcock. The sheath hub includes a hemostasis valve and a suture ring. A 4-way stopcock is affixed to the proximal end of the side port extension. The Bioteq Sheath Introducer assembly includes a vessel dilator that rotates securely with the sheath introducer hub and guidewire which is cleared by the Food and Drug Administration (K920884).

The sheath introducer is available in 5 French (F) to 7F sizes in length of 11cm or 23cm. The vessel dilator is tipped specifically to accept either a 0.038 inch or a 0.035 inch diameter guidewire with the length of 45cm or 80cm.

5.8 Non-clinical Testing

A series of tests were performed to assess the substantial equivalence of the Sheath Introducer.

- Sterilization Validation
  - Bioburden test
  - Bioburden recovery test
  - Endotoxin test
  - Sterility test
  - Biological Indicator test
  - Bacteriostatic/Fungistatic test
  - EO residual test
  - Pyrogen test
  - Batch release report
- Packaging validation test

- Biocompatibility
  - Cytotoxicity Test
  - Intracutaneous Reactivity Test
  - Acute Systemic Injection Test
  - Sensitization Test
  - The Salmonella typhimurium Reverse Mutation Assay
  - Hemolysis Test
  - Thromboresistance Test
  - Complement Activation
  - Material-Mediated Pyrogenicity
- Performance
  - Force at Break Testing
  - Conical Fittings with 6% (Luer) Taper
  - Size Designation
  - Liquid Leakage of Sheath Introducer & Liquid Leakage through Hemostasis Valve
  - Chemical characterization
  - Radiopacity Test
  - Insertion force Test
  - Guidewire compatibility Test
  - Inspection the external surface
- Comparison Performance Testing
  - Force at Break Testing
  - Size Designation
  - Liquid Leakage
  - Insertion force
  - Kink Resistance and Recovery
  - Minimum Tensile Force Required to Remove the Dilator From the Sheath Hub
  - Stiffness

All the test results demonstrate the substantial equivalence of Sheath Introducer, which meets the related requirements and its intended use.

5.9 Clinical Testing

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

5.10 EMC and Electrical safety

The devices do not require EMC/Electrical Safety evaluation.

5.11 Substantial Equivalence Determination

The Sheath Introducer submitted in this 510(k) file is substantially equivalent in intended use, design, technology/principles of operation and performance to the cleared Merit Prelude™ Sheath Introducer which is the subject of K050962. Differences between the devices do not raise any new issues of substantial equivalence.

Items \ product	Proposed device	Predicate device
	Sheath Introducer	Merit Prelude™ Sheath Introducer
Manufacturer	Bioteque Corporation	Merit Medical Systems, Inc.
Indication for Use	The Bioteq Sheath Introducer is intended to provide access and facilitate the percutaneous introduction of various devices into veins and/or arteries while maintaining hemostasis for a variety of diagnostic and therapeutic procedures.	The Merit Prelude™ Sheath Introducer is intended to provide access and facilitate the percutaneous introduction of various devices into veins and/or arteries while maintaining hemostasis for a variety of diagnostic and therapeutic procedures.
Regulation Number	870.1310	870.1310
FDA 510(k) No.	N/A	K050962

Classification	Class II	Class II
Device Description	Bioteq Sheath Introducer consists of a sheath introducer with side port extension and stopcock. The sheath hub includes a hemostasis valve and a suture ring. A 4-way stopcock is affixed to the proximal end of the side port extension. The Bioteq Sheath Introducer assembly includes a vessel dilator that rotates securely with the sheath introducer hub and guidewire.	Merit's *Prelude* consists of a sheath introducer with side port extension and stopcock. The sheath hub includes a hemostasis valve and a suture ring. A 3-way stopcock is affixed to the proximal end of the side port extension. The *Prelude* assembly includes a vessel dilator that snaps securely into the sheath introducer hub.
Product specifications		
Sheath length	11/23 cm	11/23 cm
Sheath French Size	5~7 Fr	4~8 Fr
Guidewire Diameter	0.038” & 0.035”	0.038” & 0.035”
Guidewire Length	45/80 cm	80 cm
Contents	Sheath Introducer, Dilator, Guidewire	Sheath Introducer, Dilator, Guidewire
Sterilization method	Ethylene Oxide Gas Sterilization	Ethylene Oxide Gas Sterilization
Materials		
Sheath tube	ETFE	HDPE
Dilator tube	Polypropylene	Polypropylene
Guide wire	Stainless steel	Stainless steel
Side tube	PVC	polyurethane

5.12 Similarity and differences

The proposed device has the same technological characteristics as the predicate device. The differences between the proposed device and the predicate device are Sheath French Size, Guidewire Length and the materials of Sheath tube and Side tube. ETFE and HDPE are commonly used materials in sheath introducer. We have evaluated and reviewed these materials, and the proposed device has tested on safety and performance tests and the results were complied with the test requests. Therefore, the differences of proposed device and predicate device did not raise any problems of safety or effectiveness. The proposed device is substantially equivalent to the predicate device in design, operation, intended use, method of preparation, and performance claims.

5.13 Conclusion

After analyzing bench tests, device description and intended use/indications for use, it can be concluded that Sheath Introducer is substantially equivalent to the predicate device.