K102633

510(k) SUMMARY

SEP - 9 2011

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR §807.92

1. Submitter's Name: **BIOTEQUE CORPORATION**

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Contact: William Lee / President

2. Device Name :

Trade Name: **BIOTEQ® ANGIOGRAPHIC CATHETER**

Model No. BT-ACX Series , X=4,5,6

Common Name: ANGIOGRAPHIC CATHETER

Classification name: catheter, intravascular, diagnostic

3. Device Class: **BIOTEQ® ANGIOGRAPHIC CATHETER** has been classified as

Regulatory Class: II
Product Code: DQO
Panel : Cardiovascular
Regulation Number: 21CFR 870.1200

4. Predicate Device:

- **5 FR AND 6 FR INFINITI ANGIOGRAPHIC CATHETER (K970854)** marketed by **CORDIS CORP.**
- **Summary of Technological Characteristics in Comparison to Predicate device:** BIOTEQ® ANGIOGRAPHIC Catheter has the same intended use and employs a similar method of operation and design as compared to the predicate devices. Both the new and predicate devices consist of a proximal connector, shaft, and distal tip. Both the new and predicate devices are comprised of similar materials and serve as passive conduits for the delivery of contrast media under high pressure.

5. Device Description: The **BIOTEQ® ANGIOGRAPHIC CATHETER** is with the braided proximal shaft. The distal shaft of the catheter has variety configuration and the tip is made soft to minimize trauma to the vessel wall. It consists of the following major components:

- Soft Tube
- Braiding tube
- Screw Cap
- F.L.L. Adapter
- Adaptor Butterfly

6. Intended Use: The **BIOTEQ® ANGIOGRAPHIC Catheter** is intended for use in the delivery of radiopaque contrast media to selected sites in the coronary and peripheral vasculature. The device is for single use only. This device is not intended for use in the neurovasculature

7. Performance Summary: Performance testing was conducted on the BIOTEQ® ANGIOGRAPHIC Catheter to establish substantial equivalence. Testing was conducted according to protocols based on international standards and in-house requirements and included dimensional and functional testing. Additionally, the catheters were subjected to biocompatibility testing per ISO 10993.

- Physical performance test including:
  Surface Requirements, Corrosion Resistance, Strength Test , Leakage Tests (under positive pressure and vacuum), Flow Rate Test, Torque Strength Test, Flexibility and Kink test, and Dimensional Verification, Particle Test , the Catheter Twist Transmitting Test, Catheter Shape Retention, Test for freedom from leakage and damage under high static pressure conditions, aged 3-year shelf life testing.
- Packaging Tests
- Biocompatibility Tests:

- Intracutaneous Reactivity Study
- Guinea Pig Maximization Sensitization Study
- Cytotoxicity Testing
- Intramuscular Implant Study – 1 week Duration
- Acute Systemic Injection Study
- Hemolysis — direct and indirect contact
- Thrombogenicity Study – ISO
- Salmonella Typhimurium Reverse Mutation Assay (Ames Test)
- Complement Activation Test
- Material Mediated Pyrogenicity

• Eto sterilization Validation Study

8. Conclusions:

The information and data provided in this 510(k) Notification establish that the BIOTEQ® ANGIOGRAPHIC Catheter is substantially equivalent to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Bioteque Corporation
c/o Ms. Jennifer Reich
Harvest Consulting Corp.
2904 N Boldt Drive
Flagstaff, AZ 86001

SEP - 9 2011

Re: K102633
Trade Name: Bioteq® Angiographic Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic intravascular catheter
Regulatory Class: Class II
Product Code: DQO
Dated: August 11, 2011
Received: August 22, 2011

Dear Ms. Reich:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K102633

Device Name: **"BIOTEQ" Angiographic Catheter**
BIOTEQUE CORPORATION

Indications for Use:

The "BIOTEQ" Angiographic Catheter is indicated for the delivery of radiopaque contrast medium to selected sites in the vascular system.

The device is for use in the coronary and peripheral vasculature, and not for use in the neurovasculature.

Prescription Use V AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K102633