K 03 2292

MAR 2 2 2004

510(K) SUMMARY

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
   Address: Suite 402, 4F, No.136, Sec.3,Jen-Ai Road, Taipei, Taiwan, .R.O.C.
   Phone: 886-2-2708-6716
   Fax: 886-2-2707-6610
   Contact: Mr. William Lee (General Manager)

2. Device Name
   Trade Name: BIOTEQ® A. V. FISTULA NEDDLE SET WITH SAFETY FLEX
   Common Name: A. V. FISTULA NEDDLE SET WITH SAFETY FEATURE
   Classification Name: Catheter,Intravascular,Therapeutic,Short-term Less Than 30 days

3. Classification: Class II Panel: 78 Product Code: FOZ & FIE

4. Predicate Device: JMS A.V. FISTULA NEEDLE WingEater (K 010406)

5. Device Description: The BIOTEQ® A. V. FISTULA NEDDLE SET WITH SAFETY FLEX consists of the following major components:
   ① Protection Cap
   ② Needle Cannula
   ③ Butterfly Wing
   ④ Needle Hub
   ⑤ *Safety Flex*
   ⑥ Small Pinch Clamp
   ⑦ PVC Tubing
   ⑧ Female Luer
   ⑨ Cap for Female Luer
   These components assembled together as BIOTEQ® Arterial-Venous Fistula (A.V.F) Needle Set with Safety Flex for use during hemodialysis procedures. The Safety Feature(Safety Flex) aids in prevention of needle-sticks injuries when removing and discarding needles after dialysis session. Various models of needle size manufactured such as 14 gauge, 15 gauge, 16 gauge, 17 gauge.

6. Intended Use: Indication For Use:
   The BIOTEQ® Arterial-Venous Fistula (A.V.F) Needle Set with Safety Flex is used for temporary cannulation for vascular access for extracorporeal blood treatment. The device is intended for single use only and is for temporary catheterization of less than 30 days. The Safety Feature(Safety Flex) aids in prevention of needle-sticks injuries

when removing and discarding needles after dialysis session.

7. Performance Summary: In terms of Physical specification, Chemical specification, Biological specification & Sterilization Specification, the device conforms to applicable standards included ISO 10993 series, ISO 11607-1, ISO 11135, USP Pyrogenic standards & related standards----etc.

8. Conclusions:

The BIOTEQ® Arterial-Venous Fistula (A.V.F) Needle Set with Safety Flex have the same intended use and similar technological characteristics as the JMS A.V. FISTULA NEEDLE WingEater (K 010406). Moreover, bench testing contained in this submission demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the BIOTEQ® Arterial-Venous Fistula (A.V.F) Needle Set with Safety Flex) is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 2 2004

Bioteque Corporation
c/o Ms. Jennifer Reich
Harvest Consulting Corporation
3892 South America West Trail
FLAGpSTAFF AZ 86001

Re: K032292
Trade/Device Name: BIOTEQ® A. V. Fistula Needle Set with Safety Flex
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Product Code: 78 FIE
Regulation Number: 21 CFR §880.5200
Regulation Name: Intravascular catheter
Product Code: 78 FOZ
Regulatory Class: II
Dated: October 22, 2003
Received: December 23, 2003

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.

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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510 (k) NUMBER (IF KNOWN): K032292
DEVICE NAME: BIOTEQ® A. V. FISTULA NEDDLE SET WITH SAFETY FLEX
BIOTEQUE CORPORATION

INDICATIONS FOR USE:

The BIOTEQ® Arterial-Venous Fistula (A.V.F) Needle Set with Safety Flex is used for temporary cannulation for vascular access for extracorporeal blood treatment. The device is intended for single use only and is for temporary catheterization of less than 30 days. The Safety Feature(Safety Flex) aids in prevention of needle-sticks injuries when removing and discarding needles after dialysis session.

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

Concurrence of CDRH, Office of Device Evaluation

Prescription Use X OR Over-The-Counter _____
(Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K032292