DEC 17 1999

510(K) SUMMARY

K993118
Page 1 of 2

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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   Phone: 886-2-2708-6716
   Fax: 886-2-2707-6610
   Contact: Mr. William Lee (General Manager)

2. Device Name
   Trade Name: **BIOTEQUE A.V. FISTULA NEEDLE SET**
   Common Name: **A.V. FISTULA NEEDLE SET**
   Classification name: NEEDLE, FISTULA

3. Classification: Class II *Panel: 78* Product Code: FIE

4. Predicate Device: **TERUMO AV FISTULA NEEDLE SET (K891062)**

5. Device Description: **BIOTEQUE A.V. FISTULA NEEDLE SET**
   Bioteque A.V. Fistula Needle Set consist of the following 6 major components: the stainless needle, protector cap for needle, the plastic butterfly wing, the PVC tubing, the female luer, the cap for female luer. These 6 major components assembled together as A.V. Fistula Needle Set for use during hemodialysis procedures. Various models of needle size manufactured such as 14 gauge, 15 gauge, 16 gauge.

6. Intended Use:
   ■ INTENDED USE:
   Bioteque A.V. Fistula Needle is used during hemodialysis. It's a part of accessory of extracorporeal system for treatment of renal failure. A.V. Fistula Needle applied on the access site of patient's vessel to obtain blood flow adequate to pass through the dialyses, and the reinfusion of dialysed blood back to patient via the fistula needle during hemodialysis.
   ■ USERS TO INSTALL THE DEVICE:
   Trained nurses or the doctors.

K993118
Page 2 of 2

■ ENVIRONMENT FOR THE DEVICE TO BE USED:

The hemodialysis center.

■ SPECIAL NOTES:

The Arterial – Venous Fistula (A.V.F.) Needle Set **must be installed by trained nurses and doctors.**
The patients can not influence the use of the device.

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 **BIOTEQUE A.V. FISTULA NEEDLE SET** have the same intended use and similar technological characteristics as the **TERUMO AV FISTULA NEEDLE SET (K891062)**. 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 **BIOTEQUE A.V. FISTULA NEEDLE SET** 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

DEC 17 1999

BIOTEQ® CORPORATION
c/o Mr. Allen Reich
Harvest Consulting, Inc.
900 N. Switzer Canyon Drive, #142
Flaggstaff, AZ 86001

Re: K993118
Bioteque A.V. Fistula Needle Set
Dated: September 20, 1999
Received: September 20, 1999
Regulatory Class: II
21 CFR 876.5540/Procode: 78 FIE

Dear Mr. Reich:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) NUMBER (IF KNOWN): K993118

DEVICE NAME: **BIOTEQUE A.V. FISTULA NEEDLE SET**
BIOTEQUE CORPORATION

INDICATIONS FOR USE:

Bioteque A.V. fistula needle set consist of a fistula needle which inserted into the site of patient's vessel to obtain blood flow adequate to pass through the dialyser and the reinfusion of dialysed blood back to patient via the fistula needle during hemodialysis .

- FEATURE:
  Bioteque A.V. fistula needle consists a large-bore (14-16-gauge) steel needle with plastic wing handle follow extension tubing and small clamp, the end of rotation female luer lock is for universal used to connect blood tubing. It's not implantable device.

- USERS TO INSTALL THE DEVICE:
  Trained nurses or the doctors.

- ENVIRONMENT FOR THE DEVICE TO BE USED:
  The hemodialysis center.

- SPECIAL NOTES:
  The Arterial – Venous Fistula (A.V.F.) Needle Set **must be installed by trained nurses and doctors**. The patients can not influence the use of the device.

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

Concurrence of CDRH, Office of Device Evaluation

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K993118

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