FEB 9 2000

510(K) SUMMARY

K992930

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

2. Device Name
   Trade Name: BIOTEQUE HEMODIALYSIS BLOOD TUBING SET
   Common Name: HEMODIALYSIS BLOOD TUBING SET
   Classification name: SET, TUBING, BLOOD, WITH AND WITHOUT ANTI-REGURGITATION VALVE

3. Classification: Class II

4. Predicate Device: FRESENIUS DISPOSABLE BLOOD LINES (K853851)

5. Device Description: **Bioteque Hemodialysis Blood Tubing Set,** consists of Arterial Line & Venous Line, is used as the conduit through which blood is taken from the patient, delivered to the dialyzer, and returned to the patient during dialysis therapy.

6. Intended Use:

■ INTENDED USE:
The BIOTEQUE Hemodialysis Blood Tubing Set(Models BT-102A, BT-102B and BT-190) is intended to serve as a conduit through which blood is taken from the patient, delivered to the dialyzer, and returned to the patient during hemodialysis therapy. The device is intended to be used for patients suffering from renal disease only.

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

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

■ SPECIAL NOTES:
The hemodialysis blood tubing sets **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 HEMODIALYSIS BLOOD TUBING SET** have the same intended use and similar technological characteristics as the **FRESENIUS DISPOSABLE BLOOD LINES** (K853851). 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 HEMODIALYSIS BLOOD TUBING SET** is substantially equivalent to the predicate devices.

K992930

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 9 2000

Bioteque Corporation
c/o Mr. Allen Reich
Harvest Consulting, Inc.
900 N. Switzer Canyon Dr., #142
Flaggstaff, AZ 86001

Re: K992930
Bioteq® Hemodialysis Blood Tubing Sets
Models BT-102A; BT-102B; and, BT-190
Dated: December 11, 1999
Received: December 14, 1999
Regulatory Class: II
21 CFR §876.5820/Procode: 78 FJK

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): ***K992930***

DEVICE NAME: **BIOTEQ Hemodialysis Blood Tubing Set**
BIOTEQUE CORPORATION

INDICATIONS FOR USE:

The **BIOTEQ Hemodialysis Blood Tubing Set** (Models BT-102A, BT-102B, and BT-190) is intended to serve as a conduit through which blood is taken from the patient, delivered to the dialyzer, and returned to the patient during hemodialysis therapy. The device is intended to be used for patients suffering from renal disease only.

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

Concurrence of CDRH, Office of Device Evaluation

Prescription Use ✓ OR Over-The-Counter _____
(Per 21 CFR 801.109) (Optional Format)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K992930