

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: 8 F-3, No. 136, Sec.3, Jen-Ai Road, Taipei, Taiwan, R.O.C.  
Phone: 886-2-2708-3188  
Fax: 886-2-2707-6610  
Contact: Mr. William Lee (General Manager)
2. Device Name  
Trade Name: **BIOTEQ® 3 in 1 Hemodialysis Blood Tubing Pack**  
Common Name: Blood Tubing Set With Transducer Protector , I.V.(INTRAVENOUS) SET and A.V.F.FISTULA NEEDLE SET  
Classification name: ACCESSORIES, BLOOD CIRCUIT, HEMODIALYSIS
3. Classification: Class II
4. Predicate Device: Nipro Blood Tubing Set for Hemodialysis with Transducer Protectors and Priming set (K972206) & (K001465)
5. Device Description: The BIOTEQ® 3 in 1 Hemodialysis Blood Tubing Packs ( BT-102DA 、 BT-102DB 、 BT-102DC 、 BT-102DD) are sets of single-use disposable components intended to provide extracorporeal access to blood of patients suffering from end stage renal disease during Hemodialysis therapy. Each set will include an arterial/venous bloodline set, and any combination of two or three component of the following items:
  - An **intravenous administration set** for use in administration of intravenous fluids to a dialysis set in conjunction with hemodialysis procedures. ,
  - **AV fistula needle set** to apply on the access site of patient vessel to draw the blood flow adequate to pass through the dialyer and reinfusion of dialysed blood back to patient vessel via the A.V. Fistula Needle Set during hemodialysis procedures. , and/or
  - A **transducer protector** for use as protective devices for pressure monitors and to help protect the sterility of the fluid pathway.**BIOTEQ® 3 in 1 Hemodialysis Blood Tubing Packs** includes 4 models (BT-102DA 、 BT-102DB 、 BT-102DC 、 BT-102DD)

⇒ **BT-102DA BIOTEQ® 3 in 1 Hemodialysis Blood Tubing Pack** consists of **three** components: a BIOTEQ® Hemodialysis Blood Tubing Set, a BIOTEQ® I.V.(INTRAVENOUS) SET, and a TRANSDUCER PROTECTOR.

⇒ **BT-102DB BIOTEQ® 3 in 1 Hemodialysis Blood Tubing Pack** consists of **three** components: a BIOTEQ® Hemodialysis Blood Tubing Set, a BIOTEQ® A.V.F.FISTULA NEEDLE SET, and a TRANSDUCER PROTECTOR

⇒ **BT-102DC BIOTEQ® 3 in 1 Hemodialysis Blood Tubing Pack** consists of **four** components : a BIOTEQ® Hemodialysis Blood Tubing Set , a BIOTEQ® I.V.(INTRAVENOUS) SET , a BIOTEQ® A.V.F.FISTULA NEEDLE SET, and a TRANSDUCER PROTECTOR.

⇒ **BT-102DD BIOTEQ® 3 in 1 Hemodialysis Blood Tubing Pack** consists of **three** components: a BIOTEQ® Hemodialysis Blood Tubing Set , a BIOTEQ® I.V.(INTRAVENOUS) SET , and a BIOTEQ® A.V.F.FISTULA NEEDLE SET.

6. Intended Use:

The **BIOTEQ® 3 in 1 Hemodialysis Blood Tubing Packs** ( BT-102DA 、 BT-102DB 、 BT-102DC 、 BT-102DD) are disposable bloodlines intended to provide extracorporeal access to the patient's blood during Hemodialysis therapy. The compatibility of available configurations is the responsibility of the physician in charge.

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® 3 in 1 Hemodialysis Blood Tubing Packs** have the same intended use and similar technological characteristics as the **Nipro Blood Tubing Set for Hemodialysis with Transducer Protectors and Priming set (K972206) & (K001465)**. 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® 3 in 1 Hemodialysis Blood Tubing Packs** is substantially equivalent to the predicate devices.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUL 9 2002

BIOTEQUE CORPORATION  
c/o Ms. Jennifer Reich  
Harvest Consulting, Inc.  
3892 South America West Trail  
FLAGSTAFF AZ 86001

Re: K013634

Trade/Device Name: BIOTEQ® 3 in 1 Hemodialysis Blood Tubing Pack  
Regulation Number: 21 CFR 876.5820  
Regulation Name: Hemodialysis system and accessories  
Regulatory Class: II  
Product Code: 78 FJK  
Dated: April 6, 2002  
Received: April 10, 2002

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). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note:* If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

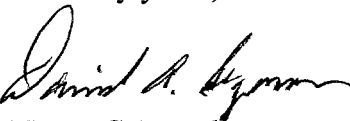
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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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 (21 CFR Part 807); 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 the labeling regulation (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. 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 Part 807.97). 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,

  
for 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): K013634DEVICE NAME: **BIOTEQ® 3 in 1 Hemodialysis Blood Tubing Packs**  
BIOTEQUE CORPORATION

## INDICATIONS FOR USE:

The **BIOTEQ® 3 in 1 Hemodialysis Blood Tubing Packs** ( BT-102DA 、 BT-102DB 、 BT-102DC 、 BT-102DD) are sets of single-use disposable components intended to provide extracorporeal access to blood of patients suffering from end stage renal disease during Hemodialysis therapy. Each set will include an arterial/venous bloodline set, and any combination of two or three component of the following items:

- **An intravenous administration set** for (use in administration of intravenous fluids to a dialysis set in conjunction with hemodialysis procedures.) ,
- **AV fistula needle set** to (apply on the access site of patient vessel to draw the blood flow adequate to pass through the dialyer and reinfusion of dialysed blood back to patient vessel via the A.V. Fistula Needle Set during hemodialysis procedures.) , and/or
- **A transducer protector** for (use as protective devices for pressure monitors and to help protect the sterility of the fluid pathway).

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

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Concurrence of CDRH, Office of Device Evaluation  
(Division Sign-Off)Division of Reproductive, Abdominal,  
and Radiological Devices

510(k) Number

K013634

OR

Over-The-Counter

Prescription Use X

(Per 21 CFR 801.109)