DEC 3 0 2004

510(K) SUMMARY

K033210

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® DOUBLE PIGTAIL URETERAL STENT SET, **or** BIOTEQ® URETERAL STENT SET(Double J Type)
Common Name:	Ureteral Stent
Classification name:	Ureteral Stent
3. Classification:	Class II
Predicate Device:	Rusch Ureter Stent Integral Set and Rusch Ureter DD Stent Sets (K982974) marketed by RUSCH INTL.
5. Device Description:	The BIOTEQ® DOUBLE PIGTAIL URETERAL STENT SET consist of a ureter stent that is completely radiopaque, coiled cylindrical or open tip with drainage holes at intervals of 5-20 mm, centimeter graduations, continuous black positioning line to indicate the direction in which the catheter tip coils, and black marking at the catheter end. The Pusher Catheter (Introducer sheath) is approximately 45cm long. The Guide Wire (Spiral stylet) is made of stainless steel with PTFE coating and a flexible safety tip and a marked rigid tip and is approximately 120 cm long. The plastic dispenser is used to protect the Guide Wire (Spiral stylet). There are also plastic clips in the set.
6. Intended Use:	**INDICATION FOR USE** BIOTEQ® DOUBLE PIGTAIL URETERAL STENT SET is intended to facilitate the temporary internal drainage of urine from the kidney to the bladder via placement endoscopically by a trained physician.

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® DOUBLE PIGTAIL URETERAL STENT SET have the same intended use and similar technological characteristics as the Rusch Ureter Stent Integral Set and Rusch Ureter DD Stent Sets (K982974) marketed by RUSCH INTL.. 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® DOUBLE PIGTAIL URETERAL STENT 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 3 0 2004

Bioteque Corporation
c/o Ms. Jennifer Reich
3892 South America West Trail
FLAGGSTAFF, AZ 86001

RE: K033210
Trade/Device Name: Bioteq Double Pigtail Ureteral Stent Set
Regulation Number: 21 CFR§876.4620
Regulation Name: Ureteral Stent
Regulatory Class: II
Product Code: 78 FAD
Dated: December 13, 2004
Received: December 16, 2004

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 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 this 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" (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,

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

Indications for Use

510(k) Number (if known): K 033210

Device Name: BIOTEQ® DOUBLE PIGTAIL URETERAL STENT SET
BIOTEQUE CORPORATION

INDICATIONS FOR USE:

BIOTEQ® DOUBLE PIGTAIL URETERAL STENT SET is intended to facilitate the temporary internal drainage of urine from the kidney to the bladder via placement endoscopically by a trained physician.

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033210

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)

See above.
NBrogdon