510(k) SUMMARY

A. Introduction

This 510(k) is for the T•REX™ biopsy forceps previously manufactured as the Bycep® biopsy forceps by Mansfield, Inc., a subsidiary of Boston Scientific Corporation. Research, development and manufacturing of the Bycep forceps has been relocated to Boston Scientific Corporation Northwest Technology Center, Inc. Several design modifications have been made to improve the performance and manufacturablility of the device. The indications for use and operation of this device remain the same.

DEC 16 1997

Submitter: Boston Scientific Corporation Northwest Technology Center, Inc.
17425 N.E. Union Hill Road
Redmond, WA 98052

Contact: Jocelyn Kersten
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Preparation Date: 10/06/97

Device Common Name: Endomyocardial biopsy forceps
Device Proprietary Name: T•REX™ Biopsy Forceps
Classification Name: Device, biopsy, endomyocardial (74DWZ) (per 21 CFR 870.4875)
Classification Panel: Cardiovascular

Manufacturing Facilities: Heart Technology Manufacturing Center, Inc.
17425 N.E. Union Hill Road
Redmond, WA 98052

B. Device Description

The T•REX™ forceps are designed to allow percutaneous access to the right or left ventricles of the heart in order to obtain diagnostic tissue samples. The forceps consist of three main components: a handle ergonomically designed for comfortable use, a body and surgical stainless steel cutting jaws.

C. Intended Use

The T•REX™ biopsy forceps is used to obtain endomyocardial biopsy specimens from the right or left ventricle via percutaneous arterial or venous approach.

D. Comparison to Predicate Device

The proposed T•REX™ forceps are substantially equivalent to the previously approved Bycep forceps. The indications for use remain the same, as well as the basic structure and operation of the device.

The following table summarizes the modifications.

Component	Bycep® Forceps (K870186)	T-REX Forceps
End-Effector and Jaw Assembly		
Jaws	Machined to sharpness	Proprietary sharpening method
Actuator links	Soft or semi-hardened stainless steel	Hardened stainless steel
Actuator/pull wire connection	Brazed	Laser welded
Housing	Single unit	Laser welded housing halves
Housing to outer jacket connection	Soldered	Laser welded
Crank length/lever angle	2.2 mm jaws, 0.0822"; 1.8 mm jaws, 0.0427" /20°	2.2 mm jaws, 0.0774"; 1.8 mm jaws, 0.0541" /15°
Attachment of actuator/actuator links and jaws/housing	Rivets	Captured by laser welded housing halves
Body		
Pull Wire	Braided stainless steel cable	Solid stainless steel wire
Shape	Flexible	Flexible and pre-curved
Liner	No liner	Liner between outer jacket and pull wire
Jacket sheath	None	Jacket sheath covering the outer jacket
Handle assembly		
Handle transition to outer jacket	Solder joint with coil strain relief around the joint	Crimped joint with integral strain relief
Handle transition to handle body	Brass handle transition press fit into straight handle body	Stainless steel handle transition press fit into tapered handle body
Finger grip/Handle body	No locking feature	Locking feature for holding jaws open during specimen removal
Finger grip insert for attachment of pull wire	Brass/Sonic welding	Aluminum/Press fit
Handle spring	None	½" diameter spring coil
Package		
Configuration	Double barrier	Single barrier
Product holder	Tray	Coil or card

1. **End effector and Jaw Assembly**

In both the Bycep models and the T•REX™ models of the biopsy forceps, the pull wire, which translates movement of the handle into opening and closing the jaws, is attached to the jaws through the end effector assembly. The Bycep models utilize brazing, soldering and rivets to construct the necessary joints in the end effector assembly. The T•REX™ models utilize laser welding to construct these joints. The jaws of the Bycep forceps are sharpened with machining while the jaws of the T•REX™ models are sharpened using a proprietary process.

In both models, when the handle is manipulated, the force is transmitted down the pull wire to the actuator. The actuator links then translate the longitudinal force from the handle into vertical force on the jaws, which opens the jaws. When the handle is released, the jaws close. Gentle force on the thumb ring of the handle ensures the jaws remain closed tightly enough to retain a cut tissue sample.

2. **Body**

The body of the forceps consists of a hollow outer jacket which contains the pull wire. The pull wire in the Bycep models is a braided stainless steel cable. The T•REX™ models contain a solid stainless steel pull wire. The solid wire allows forming by the manufacturer to produce the pre-curved models and allows the flexible models to be formed by the customer prior to use. The outer jackets of the T•REX™ models are lined and covered by a sheath. The Bycep forceps contain no liner and are not coated.

3. **Handle Assembly**

The stainless steel handle transition is crimped onto the outer jacket of the T•REX™ models. The outer sheath is heat shrunk over the distal end of the handle transition to serve as an integral strain relief. The outer jacket of the Bycep models is soldered to the brass handle transition and utilizes a stainless steel coil strain relief. The handle transitions of both models are press fit into the handle bodies. The mating portion of the handle body is cylindrical in the Bycep models and is drafted and reinforced by ribs in the T•REX™ model.

The handles of both the Bycep and T•REX models consist of a handle body, finger grip and thumb ring. Two fingers are placed into the finger grip and the thumb is placed in the thumb ring. The thumb is pulled back to open the jaws and released or pushed forward to close them. A spring coil within the handle of the T•REX™ models holds the jaws closed when the handle is in the neutral position. Also, a locking feature on the handle will secure the jaws in an open position to aid in removing the tissue sample from the jaws. The Bycep models do not contain the handle spring or the locking feature.

In both models, the handle operates the jaws via the pull wire. The pull wire is attached to the handle at the finger grip insert. This insert allows the pull wire to be captured between an aluminum disc and the insert, and held in place by a set screw. The method of attachment is the same for both models, however, in the T•REX™ models, the finger grip insert is aluminum and is press fit into the finger grip, while in the Bycep® models, the finger grip insert is brass and is sonically welded into the finger grip.

4. **Package**

Both models of the forceps are provided sterile for single procedure use. The Bycep forceps are packaged in a tray contained in a double sterile barrier. The T•REX™ forceps pre-curved models are attached to a card and the flexible models are held in a plastic coil. Both the pre-curved and the flexible models are packaged in a single sterile barrier. Sterilization and packaging testing confirmed the proposed packaging will protect the product and maintain sterility.

5. **Performance Testing (*In Vitro*)**

Comparative testing of the cutting abilities of the T•REX™ forceps and the Bycep forceps was performed. This testing confirmed the T•REX™ forceps are capable of performing the intended function of biopsy forceps, which is to obtain samples of myocardium.

E. *In Vitro* Tests

Bench testing was done to show that models of the T•REX™ forceps built with the proposed design modifications continue to be safe and effective. Testing included the modified joints and the overall tensile strength of complete devices. Testing confirmed the T•REX™ forceps met its design specifications. Therefore, BSC Northwest concludes that the T•REX™ forceps are safe and effective.

F. Biocompatibility

A biological evaluation was performed on the T•REX™ forceps to give a high degree of assurance that the final product is safe for human use. These tests included material characterization, cytotoxicity, pyrogenicity and hemocompatibility assays conducted under Good Laboratory Practices (GLP). The blood contacting portion of the device was evaluated as a whole composite following two ethylene oxide (EtO) sterilization cycles. The T•REX™ forceps were found to be compatible with biological systems.

G. Sterilization

Following final packaging and labeling, finished devices are 100% EtO sterilized to achieve a sterility assurance level (SAL) of 10^{-6}, or one nonsterile unit out of one million. Sterilization validation testing confirmed the ETO sterilization cycle is capable of delivering a minimum of 12 log reductions and confirmed a minimum Sterility Assurance Level (SAL) of 10^{-6}. The T•REX™ forceps are nonpyrogenic based on the Limulus Amebocyte Lysate (LAL) assay.

H. Clinical Tests

Clinical studies were not conducted on the T•REX™ forceps. The aspects of the device that relate to patient safety are: 1) cutting ability, 2) tensile strength of the devices, 3) biocompatibility of the materials in the fluid contact path and 4) device sterility. All of these aspects of the T•REX™ forceps have been tested, as described above, and results show the device to be safe and effective.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Rockville MD 20857

Ms. Julie Wage
Director, Regulatory Affairs
Boston Scientific Corporation
Northwest Technology Center, Inc.
17425 N.E. Union Hill Road
Redmond, WA 98052-3376

DEC 16 1997

Re: K973818
T•REX™ Biopsy Forceps
Regulatory Class: II (Two)
Product Code: DWZ
Dated: October 6, 1997
Received: October 7, 1997

Dear Ms. Wage:

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 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) 594-4648. 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/dsmamain.html."

Sincerely yours,

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K973818

Device Name: _____

Indications For Use:

Device: T•REX™ Biopsy Forceps

The T•REX™ biopsy forceps are intended to obtain endomyocardial biopsy specimens. The specimens are taken for diagnosis of diseased heart tissue or for identification and monitoring of rejection factors in a transplanted heart.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K973818

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

(Optional Format 1-2-96)