

K972672

**VIII. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS**

**A. Submitter's Name**

JUL 29 1997

1. Address

Barzell-Whitmore Maroon Bells, Inc.  
1921 Waldemere Street, Suite 310  
Sarasota, Florida 34239

2. Phone Number

(941) 917-8493

3. Contact Person

Willet F. Whitmore, M.D.

4. Summary Preparation Date

June 23, 1997

**B. Device Name**

1. Trade/Proprietary Name

BRACHYSTEPPER Stepping Unit  
BRACHYSTEPPER Needle Template Guide  
BRACHYSTAND Support and Manual Adjustment Accessory

2. Common/Usual Name

Ultrasonic Pulsed Echo Imaging System and Accessories

Manual Radionuclide Applicator System and Accessories

3. Classification Name

Ultrasonic Pulsed Echo Imaging System and Accessories

Manual Radionuclide Applicator System and Accessories

**C. Predicate Device**

1. The BRACHYSTEPPER Stepping Unit is substantially-equivalent to the following legally-marketed devices ("Predicate Devices"):

Device Name:	B & K Stepper
Manufacturer:	Brnel & Kjaer Medical
510(k) Number:	K905198 & K914945
Substantial Equivalence Date:	8/28/91 & 6/26/92

Device Name:	Civco Ultra-Step
Manufacturer:	Civco Instruments
510(k) Number:	Unknown
Substantial Equivalence Date:	Unknown

2. Predicate Devices for the BRACHYSTEPPER Needle Guide Template are:

Device Name:	Civco Seed Implant Needle Guide
Manufacturer:	Civco Medical Instruments
510(k) Number:	K875241
Substantial Equivalence Date:	4/14/88

Device Name:	B & K Stepper Matrix
Manufacturer:	Brnel & Kjaer Medical
510(k) Number:	K905198 & K914945
Substantial Equivalence Date:	8/28/91 & 6/26/92

3. Predicate Device for the BRACHYSTAND Support and Manual Adjustment Accessory for the brachytherapy system are:

Device Name:	"Martin" Immobilizing Device
Manufacturer:	Mick Radio-Nuclear Instruments, Inc.
510(k) Number:	K850571
Substantial Equivalence Date:	3/26/85

Device Name:	Ultra-Step Ultrasound Probe/Stepper Fixation Device
Manufacturer:	Civco Medical Instruments Co., Inc.
510(k) Number:	Unknown
Substantial Equivalence Date:	Unknown

**D. Device Description**

1. Function

This device is an adjustable support and manipulation apparatus and system for transrectal ultrasound imaging probes.

2. Scientific Basis

Provides pre-insertion fixation of ultrasound imaging probes, gross- and fine-adjustment capabilities, and lateral probe advancement in precise incremental units.

3. Significant Physical/Performance Characteristics

a) Design

Reusable, non-sterile.

b) Materials

Delrin and Aluminum

c) Physical Properties

Not Applicable

**E. Intended Use Statement**

1. Disease/Conditions

Volume determination of prostate and radioactive seed implantation during prostatic brachytherapy.

2. Patient Population

Males with suspected or known prostate cancer.

**F. Technological Characteristics Summary**

Manually-powered, mechanical brachytherapy system designed to provide pre-insertion fixation of ultrasound imaging probes, radiologic stepping units and needle guide templates used during prostatic brachytherapy. This system also facilitates accurate positioning of the ultrasound imaging probe, and a guide for needles carrying a radioactive seed for implantation.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Barzell-Whitmore Maroon Bells, Inc.  
c/o Marian Harding Cochran  
Regulatory Consultant  
ACCUREG, Inc.  
300 NW 82nd Avenue, Suite 402  
Plantation, FL 33324

Re: K972672  
Brachystepper Stepping Unit/Needle Guide Template  
Brachystand Support and Manual Adjustment Accessory  
Dated: July 14, 1997  
Received: July 16, 1997  
Regulatory Class: II  
21 CFR 892.1570/Procode: 90 ITX

JUL 29 1997

Dear Ms. Cochran:

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 requirement, 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/dsmamain.html>.

Sincerely yours,

Lillian Yin, Ph.D.  
Director, Division of Reproductive,  
Abdominal, Ear, Nose and Throat,  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

