K023430

510(k) SUMMARY—UF Brachytherapy Stand

Submitter Name:	Shands Teaching Hospital and Clinics, Inc. University of Florida
Submitter Address:	1600 S.W. Archer Road Gainesville, FL 32610-0315
Contact Person:	Jodi Mansfield Chief Operating Officer
Phone Number: Fax Number:	352-265-0440 352-265-0231
Date Prepared:	October 4, 2002
Device Trade Name:	UF Brachytherapy Stand
Device Common Name:	Transducer, Ultrasound, Diagnostic
Classification Name and Number:	Transducer, Ultrasound, Diagnostic 21 CFR 892.1570, 90 ITX
Predicate Device:	K972672, Barzell-Whitmore Maroon Bells, Inc.: Brachystepper Stepping Unit/ Needle Guide Template, Brachystand Support and Manual Adjustment Accessory
Device Description:	The UF Brachytherapy Stand is a manual, mechanical system that includes an ultrasound probe stabilizing stand and a stepping unit. It is for use clamped to a table top or side-rails.
Intended Use:	The UF Brachytherapy Stand is intended to be used to provide ultrasound probe alignment in planning and performing a prostate brachytherapy implant procedure.
Conclusion:	This device, with respect to materials, device characteristics and intended use, is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 24 2003

Ms. Patsy J. Trisler, J.D., RAC
Senior Consultant
Biologics Consulting Group
5610 Wisconsin Avenue, #304
CHEVY CHASE, MD 20815

Re: K023430
Trade/Device Name: UF Brachytherapy Stand
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulation Number: 21 CFR 892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: II
Product Code: 90 IYO and KXK
Dated: March 28, 2003
Received: April 1, 2003

Dear Ms. Trisler:

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 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 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 the 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" (21CFR Part 807.97) you may obtain. 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

510(k) Number (if known): K023430

Device Name: **UF Brachytherapy Stand**

Indications for Use:

The UF Brachytherapy Stand is intended to be used to provide ultrasound probe alignment in planning and performing a prostate brachytherapy implant procedure.

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

Concurrence of CDRH; Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K023430