4/1/99

Burdette Medical Systems, Inc.

206 N. Randolph Street, Suite 301
Champaign, IL 61820
Tel: (217) 239-0900
Fax: (217) 239-0905

K982696

510(k) Summary

Submitter: Burdette Medical Systems, Inc.

Address: 206 N. Randolph Suite 301
Champagne IL 61820

Phone number: (217) 239-0900

Fax number: (217) 239-0905

Contact person: Everette C. Burdette, Ph.D.

Date prepared: July 27, 1998

Trade name: Interplant™

Common name: Brachytherapy dose planning and implant system

Classification name: 892.5050 Medical charged-particle radiation therapy system Class II

Substantial equivalence claimed to:
1. Multimedia Medical Systems, Inc. **B3DTUA TherapacPLUS** dose planning
2. SSGI **Prowess 500** and **Prowess 2000** dose planning **K924240**
3. CIVCO Medical Instruments **Ultra-Step** stepper **K875241**
4. B&K Medical Systems **HP-100** stepper/stand
5. Tayman Medical **Accuseed** stand/stabilizer **K963302**
6. **COTAN** stand/stabilizer
7. **Northwest** stand/stabilizer
8. Maroon Bels, Inc. **Brachystand** and **Brachystepper K972672**

Description:

The Interplant™ system for brachytherapy was developed to address the need for a comprehensive system and procedure for prostate seed implants. The Interplant™ system compresses the requirement for separate multiple procedures into one online setting.

This product integrates all of the delivery system components (needles, template guide, probe stepper) with the dose planning system for 125-Iodine (^{125}I) and 103-Paladium (^{103}Pd) implants. The system is designed for real-time dose planning in the Operating Room

(OR) and for performing post-implant seed localization assessment. Real time ultrasound image plane acquisition with automatic probe position determination makes it possible to complete the image acquisition needed for dose planning within about a minute. The interplant™ system provides the needed components for seed implant procedures except the seeds themselves and uses existing ultrasound imaging equipment. This will enable the physician to focus on the procedure, providing immediate feedback for improved quality assurance.

Intended use:

The Burdette Medical Systems, Inc. interplant™ system is used to provide precision ultrasound probe alignment and radioactive seed implantation in the treatment of prostate cancer. The system will allow volume and dose calculation, image visualization, and post-treatment seed localization.

Summary of technological characteristics:

The Real-Time Brachytherapy Radiation Seed Implant Program and System includes all technology, computer software and hardware, and methods associated with the implant of radioactive "seeds" or pellets in the prostate. System elements include the user interface, real-time image acquisition, image contouring, dose calculation and display software, dose volume histograms, isodose surface contours, post-implant seed localization, and the patient scheduling spreadsheet software.

The System consists of a two-dimensional and three-dimensional image visualization and brachytherapy dose system employing 2D ultrasound imaging for use in radioactive seed implants of the prostate. The software for the brachytherapy seed implant and dose calculation system was developed on a Pentium-based processor with supporting graphics and digitizing hardware.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 1999

Everette C. Burdette, Ph.D.
President
Burdette Medical Systems
206 N. Randolph, Suite 301
Champaign, IL 61820

Re: K982696
Interplant™ (Brachytherapy Dose Planning and Implant System)
Dated: February 14, 1999
Received: February 24, 1999
Regulatory class: II
21 CFR 892.5730/Procode: 90 MUJ

Dear Dr. Burdette:

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 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. 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) 594-4613. 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/dsma/dsmamain.html".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive, Abdominal, Ear, Nose and Throat, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K982696

Device Name: Interplant™

Indications for Use:

The Burdette Medical Systems, Inc. Interplant™ system is used in planning and performing a prostate brachytherapy implant procedure to provide ultrasound probe alignment and radioactive seed implantation. The Interplant™ device will use standard 125-Iodine (^{125}I) or 103-Paladium (^{103}Pd) isotope permanent implant radiation seeds for the treatment of prostate cancer. The system will allow volume measurement and dose calculation, relevant prostate anatomy and dose visualization, and post-treatment seed localization.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use_____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K982696