

NOV 5 1998

**Summary of 510(k)**  
Safety and Effectiveness Data for MMS•TherpacPLUS B3DTUI

K982821

**Prepared:** August 6, 1998

**Submitter:** Multimedia Medical Systems, Inc.

**Address:** 400 Ray C. Hunt Drive, Suite 380  
Charlottesville, VA 22903

**Phone:** 804/977-8710

**Contact:** Alexander Crosby  
Vice President of Quality

**Common Name:** Transperineal ultrasound-guided implant prostate  
brachytherapy planning system

**Device Name:** MMS•TherpacPLUS B3DTUI, version 6.7

**Classification Name:** Treatment planning computer, CFR 892.5050

**Predicate Devices:** Multimedia Medical Systems "Therpac Radiotherapy  
Treatment Planning System", K930506  
SSGI, "Prowess 2000", K924240

**Device Description:**

Hardware Platform and Operating System:

The application runs on standard Intel PCs under Microsoft Windows® 32-bit operating systems.

The application is available on an OR-safe hardware platform. This hardware platform has electrical safety, emission control and cleaning provisions.

Peripherals and Accessories:

The application interfaces with an electromagnetic digitizer, video capture cards, printers, film scanners, as well as DICOM and other image importer and data drives and external sources.

Software Features:

The application supports image capture and importation from clinical imaging modalities sources, structure contouring and template registration, seed placement and dosimetry display for procedure planning and post-plan evaluation. Planning functions are supported by auto seed placement and dose optimization routines. The application supports post-procedure evaluation

through automatic seed identification. Both planning and evaluation functions allow plans to be printed on reports, support visualization in 2D and 3D views. The applications has two user support modules – seed source specification and database manager.

**Intended Use**

The MMS•TherpacPLUS B3DTUI is a software application for pre-operative planning and post-operative evaluation of permanent implant brachytherapy procedures for the treatment of prostate cancer. It assists physicians and medical physicists in pre-planning the patient's implant procedure and evaluating the actual post-operative results of the procedure.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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Alexandria Crosby  
Vice President of Quality  
Multimedia Medical Systems  
400 Ray C. Hunt Drive, S380  
Charlottesville, VA 22903

Re: K982821  
MMS-TherapacPLUS B3DTUI  
Dated: August 7, 1998  
Received: August 11, 1998  
Regulatory class: II  
21 CFR 892.5730/Procode: 90 MUJ

Dear Mr. Crosby:

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) 594-4613. 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,

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

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510(k) Number (if known): K982821

Device Name: MMS-THERPACPLUS B3DTUI

Indications For Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Segerson  
(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,  
and Radiological Devices

510(k) Number K982821

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)