K031975

AUG 2 9 2003

Premarket Notification [510(k)] Summary
Tab 4

Date Prepared:	April 24, 2003
Trade Name:	IMSure
Common Name:	IMRT QA Device and Monitor Unit Calculator
Classification Name:	Medical Linear Accelerator
Manufacturer's Name:	Prodigm, Inc.
Address:	585 Manzanita Ave. Chico, CA 95926
Corresponding Official:	Suzanne Wild
Title:	Director of Quality Assurance/ Regulatory Affairs
Telephone:	530-897-0937
Fax:	530-897-0934
Predicate:	K010464 RadCalc V4.0
Device Description:	IMSure is a software program designed to provide a second, independent verification of IMRT plans created on primary radiation therapy treatment planning systems. After independently calculating the imported plan and fluence maps, IMSure compares results with the imported plan and maps, and calculates the differences. This second check provides an effective QA tool for verification of the original IMRT treatment plan. IMSure also may be used to compute primary monitor unit calculations for single and multiple beams with open, blocked, and wedged fields.
Intended Use:	IMSure is intended for use as a quality assurance tool to verify IMRT treatment plans developed on any radiation therapy treatment planning system with the appropriate transfer format. IMSure will also perform primary monitor unit calculations from measured physics for plans of known geometry.

Technological Characteristics: The New Device has the same intended use and safety characteristics as the predicate device.

System Component	Device	
	LifeLine Software, Inc. RadCalc, Model V.4.0	**Prodigm, Inc. IMSure**
K number	K010464	This filing.
Application (Use)	Utilized for determination of monitor units or dose. Serves to validate those monitor units computed by the primary radiation therapy planning system. Primary means of calculating monitor units in situations where the physician does not order the user of a radiation therapy treatment plan.	Independent dose and fluence map verification software for Intensity Modulated Radiation Therapy based on Linear accelerator plans containing multi-leaf collimator leaf sequence data and fluence maps from primary IMRT treatment planning systems. Independent dose computation software for standard, simple geometry radiation therapy treatment planning and verification of monitor units based on Linear Accelerator parameters and physician prescribed dose information.
Platform	Minimum Pentium II processor, MFS network enabled	Minimum Pentium III processor, MFS network enabled
Operating system	Any MS Windows	Windows 2000 and XP
Algorithm – map verification	Single Source model	Single source model
Algorithm – IMRT dose Calculation	Single Source model, Clarkson scatter algorithm based on University of Chicago method	Three Source model, Clarkson scatter algorithm based on Stanford University method
MU Calculation Dose Algorithm	Khan (classical)	Khan (classical)
Patient Geometry Specifications	Two dimensional, graphical user interface based, based	Two dimensional, graphical user interface based
Machines supported	Commercially available Linear Accelerators with multi-modality energies and both photon and electron particles, including field blocking and linear wedge applicators for photon fluence modulation, and with 52,80 and 120 leaf Multi-leaf collimators	Commercially available Linear Accelerators with multi-modality energies and photon and electron particles, including field blocking and linear wedge applicators for photon fluence modulation, and with 52,80 and 120 leaf Multi-leaf collimators

System Component	Device	
	LifeLine Software, Inc. RadCalc, Model V.4.0	**Prodigm, Inc. IMSure**
Calculation point for IMRT QA	Fixed, iso-centric	Off-Axis calculation points incorporating modeled head scatter information and measured fluence perturbations
Calculation point for MU Calculations	Off-Axis and depth specified calculation points using measured physical data	Off-Axis and depth specified calculation points using measured physical data
Physics Data	Measured, tabular database stored, multiple linear accelerators allowed	Measured, tabular, flat file storage, multiple linear accelerators allowed
Scatter table	Measured	Measured and modeled (3-source model, Yang, et. al)
Import data	RTP link, Dicom RT for IMRT QA and MU Calculations	RTP link for IMRT QA Graphical User Interface for MU Calculations
Calibration method(s)	Iso-centric or fixed Calibration Distance	Iso-centric or fixed Calibration Distance
Export data	RTP link, Dicom RT, Paper documentation	Paper or Word documentation
User security	Two levels of user, password enabled	Three levels of user, password enabled

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 9 2003

Prodigm, Inc.
% Mr. Juergen Welte
Program Manager
TUV Rheinland of North America
1279 Quarry Lane, Suite A
Pleasanton, CA 94566

Re: K031975
Trade/Device Name: IMSure (IMRT QA Device and Monitor Unit Calculator)
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: 90 IYE
Dated: August 15, 2003
Received: August 18, 2003

Dear Mr. Welte:

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

Tab 3

Indications For Use

510(k) Number (if known): K031975

Device Name: IMSure

Indications for Use:

IMSure is indicated for use as a quality assurance tool to verify IMRT treatment plans developed on any radiation therapy treatment planning system with the appropriate transfer format. IMSure will also perform primary monitor unit calculations from measured physics data for plans of known geometry.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K031975

Prescription Use ✓ OR Over-The-Counter Use___
(per 21 CFR 801.109)