OCT 0 8 2002

Premarket Notification
MRC Systems: KonRad
Date : 1 July 2002

K022307

MRC Systems GMBH
Hans-Bunte-Str. 10
D-69123 Heidelberg
Germany
Phone: (+49) 6221-13803-00
Fax: (+49) 6221-13803-01

Date: July 1, 2002

Department of Health and Human Services
Center of Devices and Radiological Health
Office of Device Evaluation
Pre-Market Notification section

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

as required by section 807.92(c)

a. Submitter of 510(k)

Company name:	MRC Systems
Registration #	9040319
Address:	Hans-Bunte-Str.10 D-69123 Heidelberg Germany
Contact Person:	Mark-Aleksi Keller-Reichenbecher Ph.D Manager Quality Assurance and Regulatory Affairs
Phone:	(+49) 6221-13803-00
Fax:	(+49) 6221-13803-01

b. Device Name:

Trade/Proprietary Name:	KonRad
Common/Usual Name:	Radiation Therapy Planning System
Classification Name:	Accelerator, Linear, Medical, Accessory 21 CFR 892.5050 Class II.

c. Legally Marketed Predicate Device(s)

Our device is substantially equivalent to the legally marketed predicate device cited in the table below.

Manufacturer	Device	510(k) #
Nucletron	PLATO ITP	K992434

K022307

d. Description

KonRad as described in this submission is a radiation therapy treatment planning package designed to optimize multi-leaf collimator (MLC) positions or partial attenuation block shapes for intensity modulated external beam radiation therapy (IMRT). KonRad is a PC based system.

KonRad software uses defined anatomical structures for the optimization and treatment planning process. The images or contours are based on tomographic images imported via Dicom and Dicom RT protocols from various sources, e.g. CT, Virtual Simulation software etc. The users treatment machine beam data is utilized for plan calculation.

The user defines the desired dose to be delivered to the target and the surrounding structures. Values are entered to weight the optimization calculations according to the importance of reaching the dose objectives for the target and other structures. After the user starts the optimization, the software calculates the required MLC or partial attenuation block shapes needed to achieve the dose objectives. This is done for each beam simultaneously and the resulting dose distribution and DVH are displayed. Once the optimization is complete, the dose distribution and DVH are displayed for the user to evaluate. If the user is not satisfied with the results of the optimization, the input parameters can be modified and the optimization repeated until the desired results are met. When the user is statisfied, the final treatment plan can be stored and is ready for export.

The resulting treatment plan can be exported, to the appropriate delivery equipment, Linear Accelerator or Record and Verify system (R&V) via defined protocols, e.g. Dicom RT. The export of the treatment plan does not activate the delivery equipment, all information must be verified by the user prior to treatment.

e. Intended use

KonRad is intended to optimize multi-leaf collimator (MLC) positions or partial attenuation block shapes for intensity modulated external beam radiation therapy (IMRT). Once the optimization is complete the dose distribution and dose volume histogram curves are displayed for the user to evaluate.

After approval the results are exported to the delivery equipment, Linear Accelerator or Record and Verify system, for final verification before treatment delivery.

f. Summary of technological considerations

The KonRad software is substantially equivalent to the predicate device. It enhances the functionality of the defined predicate device by providing the ability to finalize the dose calculation.

02/07/01

Name: Mark Aleksi Keller-Reichenbecher Ph.D
Title: Manager
Quality Assurance & Regulatory Affairs
MRC Systems GMBH
Heidelberg, Germany

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 0 8 2002

Jörg Stein, Ph.D.
Managing Director
MRCSystems GmbH
Hans-Bunte-Strasse 10
69123 Heidelberg
GERMANY

Re: K022307
Trade/Device Name: KonRad Treatment Planning System v2.0
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: 90 MUJ
Dated: July 1, 2002
Received: July 16, 2002

Dear Dr. Stein:

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 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 this 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" (21 CFR Part 807.97). 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

K022307

510(k) Number (if known): **K022307**

Device Name: **KonRad**

Indications For Use:

KonRad is intended to optimize multi-leaf collimator (MLC) positions or partial attenuation block shapes for intensity modulated external beam radiation therapy (IMRT). Once the optimization is complete the dose distribution and dose volume histogram curves are displayed for the user to evaluate.
After approval the results are exported to the delivery equipment, Linear Accelerator or Record and Verify system, for final verification before treatment delivery.

(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)

(Optional Format 1-2-96)

David G. Segura

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K022307