SUMMARY OF SAFETY AND EFFECTIVENCESS

1. Submitter's Information:

Dated: March 28, 2003
TriMed Systems, Inc.
1804 Loehr Estates Ct.
Ballwin, MO 63021

Contact:
Sherry Zhang
VP of Quality Assurance And Regulatory Affairs

2. Common or Usual Name: Radiation Treatment Planing System
Product Name: TriMed TPS
Classification Name: System, Simulation, Radiation Therapy
RA(90)KPQ Class 2
21 CFR 892.5050
Version Number: 2.2

3. Predicate Device:

CadPlan Version 2.62
Radiation Therapy Treatment Planning System
K962950
Varian Cadplan

4. Description:

TriMed Plan is a comprehensive 3D radiation treatment planning system for modeling dose distribution of radiation of patient undergoing photon or electron therapy based on modern personal workstation running Windows NT, Windows 2000 and Windows XP. External beam dose calculations for both photon and electron machines are all in 3-dimensional volume that support coplanar and non-coplanar fields. Beam modifiers include hand block, customized block, multi-leaf collimators, and wedge. Different energies and modalities can be combined into the same plan. State-of-the-art 2D/3D graphics user interface makes the system very user friendly.

5. Intended Use:

TriMed Plan is used to plan radiation therapy treatments employing linear accelerators and other similar teletherapy devices with X-ray energy from 1 MV to 24 MV, as well as Cobalt-60, and electron energy from 4 MeV to 50 MeV. TriMed Plan uses 3D radiotherapy treatment approaches to combine modality plans, asymmetric and non-coplanar fields, total body irradiation, multi-leaf collimators, hand blocking, customized blocking, and wedges.

6. **Technological Considerations:**

   TriMed Plan has no significant differences in design, materials, energy source or other technological characteristics compared to the predicate device.

7. **Software Development and Verification:**

   Software development, validation and verification of the TriMed Plan has been conducted according to the policies and procedures discussed in the 510(k), which includes engineering diagrams, fault tree analyses, the Verification and Validation documentation, and all pertinent reference articles.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 3 2004

Ms. Sherry Zhang
VP of Quality Assurance
and Regulatory Affairs
TriMed Systems, Inc.
1804 Loehr Estates Ct.,
BALLWIN MO 63021

Re: K031088
Trade/Device Name: TriMed Plan 2.2
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: 90 MUJ
Dated: June 24, 2004
Received: June 25, 2004

Dear Ms. Zhang:

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 such 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

TriMed Systems, Inc.

Statement of Indication for Use

510(k) Number:

Device Name: TriMed Plan – Radiation Treatment Planning System

Indication for User: TriMed Plan is a radiation treatment planning software developed by TriMed Systems, Inc, running on IBM compatible personal computers with Microsoft Windows operating systems.

TriMed Plan provides radiation treatment planning capability, for both photon and electron external beam sources, to satisfy the prescription of the radiation oncology. TriMed Plan uses 3D conformal therapy treatment approaches to combine modality plans, asymmetric and non-coplanar fields, total body irradiation, multi-leaf collimators, hand blocking, customized blocking, and wedges. The resulting treatment plan from this system is to be evaluated, modified as necessary, approved and delivered by qualified medical personnel.

Prescription Use 1

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K031088

1804 Loehr Estates Ct., Ballwin, MO 63021, USA