K022411

SEP 2 0 2002

SUMMARY OF SAFETY & EFFECTIVENESS

Precision Therapy International Inc. (PTI) hereby provides the following material summarizing safety and effectiveness information for PrecisePLAN® 2.00. This information is summarized as follows:

1) PrecisePLAN® 2.00 is an enhancement to the PrecisePLAN® 1.00, which has previously been cleared for commercial distribution (K002240 8/23/2000). This enhancement to PrecisePLAN® does not raise additional types of safety or effectiveness considerations.

2) The accompanying documents provided for the user contain comprehensive information to ensure safe and effective use. Past experience with substantially equivalent predicate devices has shown our device to be safe and effective when used as directed by the accompanying documents provided for the user.

3) It is our opinion that PrecisePLAN® 2.00 does not have technological characteristics that raise additional types of safety or effectiveness questions, and that we consider them an enhancement to the existing PrecisePLAN®.

4) PrecisePLAN® 2.00 is designed to bear the CE mark affirming compliance with all relevant European Directives in force, in particular the European Medical Device Directive. As a result of this, products may be sold freely without restriction throughout the entire European Union.

5) PTI is a registered medical device establishment of assessed capability against the requirements of ISO 9001 and the Medical Device Directive 93/42/EEC Annex II.

6) PTI Quality System has been established to satisfy the requirements of ISO 9001, the Medical Device Directive 93/42/EEC Annex II, and 21 CFR 820. PTI has developed the Precise Plan 2.00 using an established and documented Quality Management System.

7) In accordance with the above requirements, all parts of the Quality System are subject to periodic and systematic internal Quality Audits. These audits are performed by trained personnel not having direct responsibilities in the functions being audited.

8) PTI has conducted risk analysis on PrecisePLAN® 2.00 and has concluded that it does not introduce hazards that raise new types of safety or effectiveness considerations. After considering the Guidance for the Content of Pre-Market Notification Submissions of Medical Devices Containing Software PTI has concluded the level of concern appropriate to the device is "Major".

9) The Quality System is subject to regular, planned and documented quality system audits conducted by external auditors from BSI (UK Notified Body) and the FDA.

Signature

July 22, 20

Mark Symons

President

Signature

7/22/02

Peter Stegagno

Director, Regulatory Affairs & Quality Assurance

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 0 2002

Mr. Peter Stegagno
Director, Regulatory Affairs
& Quality Assurance
Precision Therapy International, Inc.
3155 Northwoods Parkway NW
NORCROSS GA 30071

Re: K022411
Trade/Device Name: PrecisePLAN® Treatment Planning System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: 90 MUJ
Dated: July 22, 2002
Received: July 24, 2002

Dear Mr. Stegagno:

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.

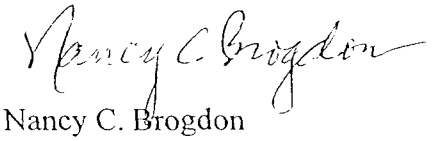
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): KO22411

Device Name: Prec*is*ePLAN® Treatment Planning System

Indication for Use:

The Prec*is*ePLAN® Treatment Planning System is intended to be used for planning the dosimetry of treatments in radiation therapy. Prec*is*ePLAN® provides 2 and 3 dimensional planning capabilities based upon user defined treatment plan parameters. As an option, the user may elect to use weight optimization functionality that suports Intensity Modulated Radiaton Therapy (IMRT). Using the IMRT functionality extends the 3-D conformal planning where geometric shaped apertures are created to cover target structure(s) and minimize exposure to surrounding organs at risk. It processes the inputs of the health care professional such that the desired radiation dose can be set on a radiation therapy delivery system.

(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. Hyman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number KO22411