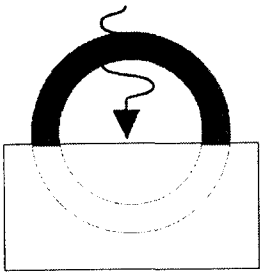
K030821

SEP 17 2003



SIMUPLAN S.L.
Miguel Hernandez 25
La Eliana
46183 Valencia
Spain
Phone: (+34) 96-274-3827
Fax: (+34) 96-272-5132

Date: March 10, 2003

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:	**SIMUPLAN S. L.**
Registration #	pending
Address:	Miguel Hernandez 25 La Eliana 46183 Valencia Spain
Contact Person:	Conrado Pla Ph.D.
Phone:	(+34) 96-274-3827
Fax:	(+34) 96-272-5132

b. Device Name:

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

c. Legally Marketed Predicate devices(s)

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

Manufacturer	Device	510(k) #
Nucletron B.V.	PLATO Brachytherapy	K983343
Nucletron B.V.	PLATO SRS	K010784

d. Description

SIMUPLAN Treatment Planning System is a computer based software that runs on a MacIntosh platform. The planning system is comprised of 2 main components; external beam and brachytherapy.

The patients' transverse slices (i.e. CT, MR) or x-ray films are imported to the system from various methods: DICOM, disk, video, scanner. From this data the patient anatomical structures and tumor site is contoured in order to generate a 3D patient model, or x-ray films displaying the implant area are imported for standard brachytherapy treatment planning. The following step in the process will be to define the treatment machine, applicators, template, seed location, or isocenter. From this information the user will select the appropriate source (brachytherapy) or beam data (linear accelerators) to be used for the planning session. Based on the target volume or reconstructed implant, the treatment source (external beam or radioactive source) and prescription dose the treatment plan will be calculated and a dose distribution will be displayed. The physician is capable of fine tuning this treatment plan before final output. The approved treatment plan is then printed out, a program card written (remote afterloading) and a hard copy of the isodose distribution is prepared for the patients' permanent record. The patient data is then saved under a unique file name in the patient data base. The program output does not directly treat the patient, all information must be confirmed by the physician prior to treatment.

e. Intended use

SIMUPLAN Treatment Planning System is intended for use in preparing individual treatment plans for patients undergoing radiation therapy treatment with external beam or brachytherapy. The program output does not directly treat the patient, all information must be confirmed by the physician prior to treatment.

f. Summary of technological considerations

The SIMUPLAN Treatment Planning System software is substantially equivalent to the predicate devices.

Name: Conrado Pla Ph.D.
Title: President
SIMUPLAN S. L.

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 17 2003

Conrado Pla, Ph.D.
President
SIMUPLAN S.L.
Miguel Hernandez 25
La Eliana, 46183 Valencia
SPAIN

Re: K030821
Trade/Device Name: SIMUPLAN Treatment Planning Systems
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: 90 MUJ
Dated: June 24, 2003
Received: June 30, 2003

Dear Dr. Pla:

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

Applicant: SIMUPLAN K030821
510(k) Number (if known): K030821
Device Name: SIMUPLAN Treatment Planning System

Indications For Use:

SIMUPLAN Treatment Planning System is intended for use in preparing individual treatment plans for patients undergoing radiation therapy treatment with external beam or brachytherapy. The program output does not directly treat the patient, all information must be confirmed by the physician prior to treatment.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)
(Optional Format 1-2-96)

Prescription Use ✓

David A. Flynn
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K030821