

AUG - 5 1997

SUMMARY OF SAFETY AND EFFECTIVENESS

- 1. Submitter's Information:** Dated: August 28, 1996
TOPSLANE
824 Ruth Dr., Pleasant Hill, CA 94523
- Contact Person:** Ann Zeng
VP of Quality Assurance And Regulatory Affairs
- 2. Common or Usual Name:** RADIATION TREATMENT PLANNING SYSTEM
Proprietary Name: ATES
Classification Name: System, Simulation, Radiation Therapy
RA (90) KPQ Class 2
21 CFR 892.5050
- Version Number:** 2.0
- 3. Predicate Device:** Theraplan V05B
Radiation Therapy Treatment Planning System
K940237
Theratronics

4. Description of Device:

The TOPSLANE ATES is a Radiotherapy Treatment Planning System (RTPS) for radiation dose planning of patients undergoing external beam treatment in the oncology clinic. ATES is using modern photon beam convolution dose calculation algorithm and electron pencil beam dose calculation algorithm. The system software is designed to be convenient and low cost to the user.

5. Statement of intended use:

The TOPSLANE product ATES is a Radiation Therapy Treatment Planning System for radiation dose planning of patients undergoing external beam treatment in the oncology clinic. ATES is used to plan radiation treatments with linear accelerators and other similar teletherapy devices with x-ray energies from 1 to 25MV, as well as Cobalt-60, and electron energies from 1 to 25 MeV.

The intended use is the same as the predicate device.

6. Statement of technological characteristics:

The ATES has no significant change in design, materials, energy source or other technological characteristics compared to the predicate device.

The intended use and the technological characteristics are the same as the predicate device and therefore we believe it is substantially equivalent to it.

7. Differences:

The minor configuration differences between the ATES and the predicate device do not alter the intended use or affect the safety and effectiveness of the ATES when used as labeled.

8. Special Controls:

Although there are no performance standards established by the FDA for these devices, ATES has been designed, and manufactured to meet the following standards:

IEC 601-1 Medical electrical equipment - General requirements for safety
IEC 601-1.1 Safety requirements for medical electrical systems
IEC 878 Graphical symbols for electrical equipment in medical practice

The device and its development process also comply with the FDA, CDRH, ODE, August 29, 1991, Reviewer Guidance for Computer Controlled Medical Devices Undergoing 510(k) Review.

9. Performance Evaluations:

Performance tests were conducted and the results indicated that the system consistently performed within the design parameters and equivalently to the predicate device.

THE END



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Ann Zeng
VP of Quality Assurance
and Regulatory Affairs
TOPSLANE
824 Ruth Drive
Pleasant Hill, CA 94523

Re: K963451
Anti-Tumor Radiation Treatment
Planning System (ARTP)
Dated: June 19, 1997
Received: June 23, 1997
Regulatory Class: II
21 CFR 892.5050/Procode: 90 IYE

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Dear Ms. Zeng:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsmmain.html>.

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K963451

Device Name: Anti-Tumor Radiation Treatment Planning System (ARTP)

Indications For Use:

The ARTP (Anti-Tumor Radiation Treatment Planning System) is a radiation therapy treatment planning system for radiation dose planning and simulation of patients undergoing external beam treatment in the oncology clinic. ARTP is used to plan and simulate radiation treatments with linear accelerators and other similar teletherapy devices with x-ray energies from 1 to 25MV, as well as Cobalt-60, and electron energies from 1 to 25 MeV.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over The Counter Use _____

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K963451