K964607

MAY 28 1997

Appendix 2
510(k) Summary

Submitter:	Theratronics International Limited 413 March Road, P.O. Box 13140 Kanata, Ontario Canada K2K 2B7
Phone:	613-591-2100
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Contact person:	E. S. Martell, Vice President Quality Assurance & Regulatory Affairs
Date:	October 21, 1996
Trade name:	Theratron 1000E
Common name:	Cobalt Teletherapy device
Classification name:	Radionuclide Radiation Therapy System
Equivalent device:	Theratron 1000, 510(k) number K894165/B.

Description of device:

The Theratron 1000E consists of a source head, collimator, gantry, main frame, base, controls and a pendulum or beamstopper style counterweight. The design of this device is similar as the predicate device Theratron 1000 with improved safety features and radiation shielding in the collimator area of the unit head assembly.

Intended use of device:

The unit is intended to be used in:

- delivering the intended dose at a specified position;
- delivering the radiation in accordance with the selected relationship of the radiation to the patient (fixed or moving beam therapy, beam modifying device, etc.);
- delivering the radiation without causing unnecessary risk to the patient, the operator, other persons, or the immediate environment.

Summary of comparison to predicate device.
See Appendix 5.

Summary of conclusions drawn from nonclinical tests
The Theratron 1000E development and validation is in compliance with Theratronics product development procedures. The validation demontrates that the device meets its published specifications, performs as well or better than the predicate device to which it is substantially equivalent, and is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 28 1997

E. S. Martell
Vice President
Quality Assurance and Regulatory Affairs
THERATRONICS International Limited
413 March Road
P.O. Box 13140
Ontario, Canada K2K 2B7

Re: K964607
THERATRON T 1000E Cobalt Teletherapy Unit
Dated: February 27, 1997
Received: March 3, 1997
Regulatory Class: II
21 CFR 892.5750/Procode: 90 IWD

Dear Mr. Martell:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4591 for Radiology devices, or 594-4613 for Ear, Nose and Throat devices. 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/dsmamain.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

Number (if known): K964607

Device Name: THERATRON 1000E

Indications For Use:

A Cobalt Teletherapy unit is a device by which gamma radiation is delivered for the treatment of cancer under the direction of health care professionals in a radiation therapy clinic.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Jegerson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K964607

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)