

DEC 4 1998

Theratron Elite 510(k) Summary

Submitter: Theratronics International Limited
413 March Road, P.O. Box 13140
Kanata, Ontario
Canada K2K 2B7

Phone: 613-591-2100
Fax: 613-592-3816

Contact person: E. S. Martell, Vice President Quality & Regulatory Affairs
Date: Nov 16, 1998

Trade name: Theratron Elite
Common name: Cobalt Teletherapy device
Classif. name: Radionuclide Radiation Therapy System
Equivalent device: Theratron 780E (K964606), Theratron 1000E (K964607).

Description of device:

The Theratron Elite consists of a source head, collimator, gantry, main frame, base, controls and a pendulum or beam-stopper style counterweight. The design of this device is similar to predicate devices Theratron 780E and 1000E. The key difference is that the 'push-button' style control console on the predicate devices has been replaced with a modern PC based remote control console with graphic user interface and 'Record and Verify' communication capability.

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 Section 2.

Summary of conclusions drawn from nonclinical tests

The Theratron Elite development and validation is in compliance with Theratronics product development procedures. The validation demonstrates 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.



DEC 4 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850E.S. Martell
Vice President
Quality and Regulatory Affairs
Theratronics International, Ltd.
413 March Road
Kanata, Ontario
CANADARe: K983917
Theratron Elite 80 and 100
Dated: October 29, 1998
Received: November 4, 1998
Regulatory class: II
Procode: 90 IWB
CFR 892.5750

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 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 at (301) 443-6597.

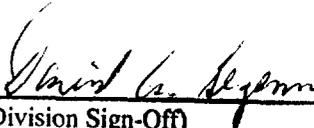
Sincerely yours,

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

3. Intended use of device

The device is intended to be used in:

- Delivering the intended dose of radiation 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.



(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K983917

Prescription Use _____
(Per 21 CFR 801.109)

