

September 29, 1997

U.S. Nuclear Regulatory Commission Washington, D.C. 20555 Attention: Douglas Broaddus Mail Stop T8-F5

Subject:

SUBMISSION OF THERATRONICS INTERNATIONAL LIMITED

**QA MANUAL** 

Enclosed please find the most current copy of the THERATRONICS INTERNATIONAL LIMITED Quality Assurance Manual, Revision U, 5.00-QA 00 dated March 1997, for your review and retention.

The Manual is being submitted in support of the current applications for device registry for the therapy unit models T780E and T1000E which are presently in your possession. The Quality Assurance Manual states the policies and responsibilties for quality and describes the functional procedures as well as the system under which the aforementioned devices are designed, manufactured, tested and serviced.

Also, the latest revision of the Manual is being submitted to replace any older versions which you may have. Mr. John Lubinski of your department who recently visited THERATRONICS stated that documentation of the THERATRONICS Quality Assurance programme was outdated. Revision U of the Manual supercedes all other revisions.

If you require any other information, do not hesitate to call, facsimile or E-Mail at the following respectively: (613) 591-2177, (613) 592-3816, beatty.d@theratronics.com.

C.D. Beatty

Regulatory Affairs

Enclosure:

413 March Road P.O. Box 13140 Kanata Ontario Canada K2K 287 (613) 591-2100 Fax (613) 592-3816

