

510(k) Summary

K961400

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This summary is submitted in compliance with the FDA interim rule as published 28 April 1992 in 21 CFR 807.92:

- (a) (1) Submitted by: Scanditronix Medical AB
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- Date of preparation: 28 Mar 1996
- (2) Trade name of device: Scanditronix Medical RFA-300, LDA Utility
- Common name: Radiation field analyzer, LDA
- Classification name: (Accessory to)Radionuclide radiation therapy system, §892,5750; and X-ray radiation therapy system, §892,5900.
- (3) Identification of predicate marketed device: RFA-300 (Scanditronix Medical AB, or legally K934303 / S1), Wellhöfer WP600 (Medical Physics instrumentation, K882770) and Wellhöfer MDA (Medical Physics instrumentation).
- (4) Description of the devise:
- The Scanditronix Medical RFA-300, LDA Utility is an extension to the RFA-300 system used to measure radiation therapy beam intensity. For use, a complete RFA-300 system is needed extended with the following equipment:
1. Multichannel electrometers emX which provides 12 independent electrometer channels each or a DPD-510 which provides 10 independent electrometer channels.
 2. Linear Detector Array LDA-11 (11 detectors) or LDA-25 (25 detectors).
 3. PC-based software providing control, display, calibration and save functions.
- (5) Intended uses:
- The Scanditronix Medical RFA-300, LDA Utility is used to more effectively perform radiation therapy beam measurements including acceptance testing, trimming information, routine beam checks and

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quality assurance measurements and on-line data analyses using personal computer (PC) monitor.
These uses are similar to those of the predicate identified in section (3) of this Summary.

(6) Technological comparison:

The Scanditronix Medical RFA-300, LDA Utility, is similar to the predicate marketed device in that radiation beam measurements are made using solid state, single or multi, detectors connected to electrometers which converts data into formats suitable for tabulation, display, or transfer to therapy planning systems. Control of the system is based on the software in a PC which also provides for display, storage, or transfer of data.

(b) (1) Non-Clinical tests:

Comparison of operational characteristics for the Scanditronix Medical RFA-300, LDA Utility and the predicate product show similar results that are suitable for their intended purpose. To minimize potential electrical hazards, Scanditronix Medical adheres to recognized and established industry practice, and all devices are subject to final performance testing. The Scanditronix Medical RFA-300, LDA Utility is designed for conformance with IEC 601-1 standards for electrical isolation, and meets electrical performance standards for CSA and UL certifications. In addition, IEC-601C standards for accelerator performance are used as minimum criteria of measurement and data processing capabilities of the Scanditronix Medical RFA-300, LDA. The Scanditronix Medical RFA-300, LDA Utility has been tested and found to fulfil the requirements concerning electromagnetic compatibility according to the standard IEC 601-1-2 (see appendix XVIII).

(2) Clinical tests:

Due to the fact that the system is not directly involved with patients, no clinical testing was performed.

(3) Test conclusions:

Testing of operational parameters for the Scanditronix Medical RFA-300, LDA Utility, indicate that the device is safe, that it provides appropriate verification and dose measurements of radiation beams, and that it performs as well as or better than the legally marketed predicate device identified in section (3) of this summary.

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