

K953391

**SUMMARY OF SAFETY AND EFFECTIVENESS**

MAR - 7 1996

1. **Submitter's Information:** Dated: November 27, 1995  
Siemens Medical Systems  
Oncology Care Systems Group  
4040 Nelson Avenue Concord, CA 94520
- Contact Person:** Kenneth R. Michael, Pharm.D.  
Vice President Regulatory Affairs and Quality Assurance
2. **Common or Usual Name:** TREATMENT PLANNING SYSTEM (TMS) ~~✓~~  
**Proprietary Name:** TMS ✓ 2.10  
**Classification Name:** Medical Charged-Particle Radiation Therapy System  
21 CFR 892.5050  
Class II, Product Code: RA 90 LHN
3. **Predicate Device:** SCANDIPLAN  
3-Dimensional Radiation Therapy Treatment Planning System K914926  
Scanditronix

**4. Description of Device:**

The Siemens Medical Systems, Oncology Care Systems Group TMS is a 3D Radiotherapy Treatment Planning (RTP) system for radiation dose planning of patients undergoing external beam treatment in the Oncology clinic. TMS is a 3-D system, using modern algorithms for dose calculations. A convolution/superposition pencil beam algorithm is used for photons and a generalized Gaussian pencil beam model is used for electrons. The system software is designed to lead the user through a logical flow planning process.

**5. Statement of intended use:**

TMS is used to plan radiation treatments with linear accelerators and other similar teletherapy devices with x-ray energies from 4 to 50MV, as well as Cobalt-60, and electron energies from 4 to 50 MeV. TMS will plan the 3D radiotherapy treatment approaches of combined modality plans, asymmetric and noncoplanar fields; total body irradiation (TBI); multi-leaf collimators (MLC); motorized and dynamic wedges; customized blocking; compensating filters (CF); and bolus.

## **SIEMENS TMS 510(K) Notification**

Export capabilities exist as part of TMS to verify beam and patient data, dose planning results, and provide on-line information to block-cutting devices and (CF) milling machines.

The intended use is the same as the predicate device.

### **6. Statement of technological characteristics:**

The Treatment Management System 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 Treatment Management System and the predicate device do not alter the intended use or affect the safety and effectiveness of the TMS when used as labeled.

### **Special Controls:**

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

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

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.

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

ATTACHMENT H