

**SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION
SUPPORTING A DETERMINATION OF SUBSTANTIAL EQUIVALENCE**

I. GENERAL INFORMATION

K955059 JUN - 7 1996

Class II: 21 CFR 870.2300 Cardiac monitor (Cardiotachometer and Rate Alarm).
21 CFR 870.2450 Medical Cathode-Ray Tube Display

Class III: 21 CFR 870.1025 Arrhythmia detector and alarm.

Common Names:

Olympus Communications Network Communications Network, Patient Monitoring Network, Information Network;
SC 3000 Workstation Central Station Monitor, Central Nursing Station;
SC 3000 Remote Display Slave Display, Repeater Display;

Device Trade Names:

Siemens Olympus Communications Network
SC 3000 Workstation
SC 3000 Remote Display

Intended Uses:

Olympus Communications Network To act as a communications network for the SC 9000/9015 (K946306) and SC 6000/6000P (K944350) Patient Monitoring Systems, the SC 3000 Workstation, R 50 (K944350) and R 100 Recorders, and laser printers.
SC 3000 Workstation To act as a central monitoring device for the SC 9000/9015 (K946306) and SC 6000/6000P (K944350) Patient Monitoring Systems through its connection to the Siemens Olympus Communications Network.
SC 3000 Remote Display To act as a Slave Display for the SC 3000 Workstation.

Establishment Name and Address:

Siemens Medical Electronics, Inc.
16 Electronics Avenue
Danvers, MA 01923

Establishment registration Number:

1220063

Performance Standard:

None established under Section 514 or Section 358

II. SAFETY AND EFFECTIVENESS INFORMATION

ELECTRICAL:

Compliance with Standards:

Olympus Communication and Power Supply (CPS): IEC 601-1, UL 544

SC 3000 Workstation Unit: UL 433, EN 60950, CE Mark

SC 3000 Remote Display: UL 1950, CSA 22.2 No. 950, EN 60950, CE Mark

OPERATION:

The device labeling contains instructions for use which assures safe and effective use of the devices.

DEVELOPMENT:

Medical device development is conducted in accordance with an approved Siemens Product Planning Process and Engineering Process. Product specifications, hazards analysis, software development plan and device test plan are required parts of the device development process. Qualification test results which demonstrate that the device performs in accordance with its specification are required before product release.

III. SUBSTANTIAL EQUIVALENCE

The devices listed below have the same intended uses and technological characteristics:

Siemens' New Device	Equivalent Device (Siemens)	K #	Equivalent Device (Marquette)	K #
Olympus Communications Network	SIRENET Communications Network	K920445	Unity Network	applicable to: K900598 K901072 K912799
SC 3000 Workstation and Remote Display	SIRECUST 120/121C Central Station SIRECUST 120/121S Slave Display	K920445 K920445	CentralScope™ 12 Central Station Remote Color Display	K901072 K901884