

Appendix 1

K965004

510(k) Summary C.A.R.E. VISION Option for SOMATOM Plus 4 CT System

Submitted by:

Siemens Medical Systems, Inc.
186 Wood Avenue South
Iselin, NJ 08830

December 13, 1996

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

1. **Contact Person:**

Ms. Jing Zhang
Phone: (908)321-4927 Fax: (908)321-4841

2. **Device Name and Classification:**

Trade Name: C.A.R.E. VISION for the SOMATOM Plus 4 CT
Classification Name: Computed Tomography X-ray System
Classification Panel: Radiology
CFR Section: 21 CFR §892.1750, Class II
Device Code: 90JAK

3. **Substantial Equivalence:**

The C.A.R.E. VISION option operating on SOMATOM Plus 4 CT scanner is substantially equivalent to the following devices:

- 1) SOMATOM Plus 4 CT
Siemens Medical Systems, Inc., for scanning
- 2) Real Time Reconstruction System Option for Xpress/SX CT System
Toshiba America Medical Systems, Inc. for real time image reconstruction and display

4. **Device Description:**

The C.A.R.E. VISION option is a new scan mode added to the SOMATOM Plus 4 CT scanner. The option can be installed in the factory or in the field via an upgrade kit consisting of hardware, software and firmware.

SIEMENS

Under C.A.R.E. VISION, three to nine images are reconstructed and displayed per second, effectively simulating a real-time display presentation. More than one C.A.R.E. VISION scans can be set-up and performed one after the other. C.A.R.E. VISION can also be mixed with other scan modes. Switch to SEQUENCE scan mode can be initiated any time during C.A.R.E. VISION thus a particular phase of the operation can be displayed in enhanced image quality.

5. **Intended Use of the Device:**

The C.A.R.E. VISION is intended to be used for instant display of CT images during interventional procedures using CT scanners. Instant image reconstruction of 3-9 images per second allows the physician to watch the placement of an interventional instrument real time.

6. **Summary of Technological Characteristics of the Device Compared to the Predicate Device:**

The C.A.R.E. Vision has the same technological characteristics as the Real Time Reconstruction System Option for Xpress/SX CT System from Toshiba America Medical Systems, Inc. They both provide real time reconstruction and display of the CT images that can be used in conventional interventional CT exams.


Kathleen Rutherford
Manager, Regulatory Submissions
Siemens Medical Systems, Inc.