

510(k) Summary

Siemens SOMATOM Plus 4 Computed Tomography (CT) Scanner with Somaris 4/B30 Software

Submitted by:

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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:

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2. Device Name and Classification:

Trade Name:	SOMATOM Plus 4 CT Scanner
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750
Device Class:	Class II
Device Code:	90JAK

3. Intended Use:

The SOMATOM Plus 4 CT Scanner is intended to produce cross-sectional images of the body by computer reconstruction of X-ray transmission data from either the same axial plane taken at different angles or spiral planes* taken at different angles.

* The axial planes resulted from the continuous rotation of detectors and X-ray tube and the simultaneous translation of the patient.

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4. Substantial Equivalence:

The new SOMATOM Plus 4 CT Scanner is substantially equivalent to the following devices in commercial distribution:

- SOMATOM Plus 4 CT Scanner, K941546
Siemens Medical Systems, Inc.
- HiSpeed Advantage, K940606
GE

5. Device Description:

The SOMATOM Plus 4 with Somaris 4/B30 software is a whole body computed tomography X-ray scanner, which features a continuously rotating tube-detector system and functions according to the fan beam principle.

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

The SOMATOM Plus 4 operating with Somaris 4/B30 software has the same technological characteristics as the predicate Plus 4 operating with Somaris 4/B20 software, except the addition of an optional solid state detector. The change from xenon detector to solid state detector does not change the overall design and operation of the Plus 4 scanner. Since the solid state detector has a higher conversion efficiency, the low contrast resolution is improved and the image noise is reduced.


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