SIEMENS

K971054

Appendix 1

510(k) Summary
Osteo CT Option for SOMATOM CT Systems

Submitted by:

JUN 13 1997

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

March 21, 1997

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:	Osteo CT for SOMATOM AR family, and Plus 4 Computed Tomography Systems
Classification Name:	Computed Tomography X-ray System
CFR Section:	21 CFR §892.1750, Class II
Device Code:	90JAK

3. **Substantial Equivalence:**
The Osteo CT option operating on SOMATOM AR family, and Plus 4 CT scanners is substantially equivalent to the following devices:

1) 3D QCT Bone Mineral Densitometry MindWaves Software, for assessing BMD
2) SOMATOM AR family, and Plus 4 CT scanners Siemens Medical Systems, Inc., for scanning and image analysis

4. **Device Description:**
OSTEO CT is a scan/evaluation option added to the SOMATOM AR family, and Plus 4 CT scanners. It provides assessment of the bone mineral density (BMD) through the use of single energy quantitative CT technology.

An Osteo package contains 1 reference calibration phantom designed for all SOMATOM CT systems, 1 tabletop pad specially designed for

housing the reference phantom, 1 coupling pad designed to eliminate possible air bubbles between the patient and the reference phantom, 1 foam insert to prevent the phantom from moving vertically within the tabletop pad and to eliminate possible air bubbles between the table and the reference phantom, 1 pad insert to prevent the phantom from moving longitudinally within the tabletop pad, and the bone mineral density scanning/evaluation software.

5. **Intended Use of the Device:**
The Osteo CT is intended to be used for routine assessment of bone mineral content in cortical and trabecular bone. It is also applicable to assess changes in bone mineral content over time.

6. **Summary of Technological Characteristics of the Device Compared to the Predicate Device:**
The Osteo CT has the same technological characteristics as the predicate 3D QCT Bone Mineral Densitometry, except the Osteo CT is written for Siemens line of CT scanners while the predicate can take images from any CT scanners. They both use reference phantom, calculate the patient's bone mineral density (BMD) with reference to the phantom, offer a reference database, and provide BMD results in both tabular and graphical forms. The reference database and the comparison provide a reference for the clinical evaluation of bone diseases.

The Osteo software operates independent of the SOMATOM CT scanners reconstruction software, does not influence the determination of the CT numbers by the scanners, and does not affect the dosage characteristics or the imaging performance parameters of the SOMATOM CT scanners.

7. **Clinical Study and Conclusion:**
A multi-center clinical study was carried out in Europe to collect cortical and trabecular bone CT images from individuals with normal bone mineral density. The collected data, after statistical analysis, served as the reference database.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 13 1997

Jing Zhang
Technical Specialist
Siemens Medical Systems, Inc.
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Re: K971054
Osteo CT for the SOMATOM AR family and Plus 4 CT X-Ray Systems
Dated: March 21, 1997
Received: March 24, 1997
Regulatory class: II
21 CFR 892.1750/Procode: 90 JAK
21 CFR 892.1170/Procode: 90 KGI

Dear Ms. Zhang:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591 for Radiology devices, or 594-4613 for Ear, Nose and Throat devices. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Lilian Yin, Ph.D.
Director, Division of Reproductive, Abdominal, Ear, Nose and Throat, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Appendix 2

Indications for Use

510(k) Number (if known): K971054

Device Name: Osteo CT for the SOMATOM AR family, and Plus 4 CT Scanners

Indications for Use:

The Osteo CT is intended to be used for routine assessment of bone mineral content in the vertebral bodies of the lumbar and thoracical spine with high precision through the use of SOMATOM CT scanners. It is also applicable to assessment of changes in bone mineral content over time.

Concurrence of the CDRH, Office of Device Evaluation (ODE)

David A. Legrow

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K971054

Prescription Use ✓ OR Over-The-Counter Use _____
(per 21 CFR 801.109)