FEB - 3 2005

K043469

SECTION 9

510(k) SUMMARY

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

I. GENERAL INFORMATION

1. Device Name and Classification

Product Name:	***InSpace 4D***
Classification Name:	Accessory to Computed Angiographic x-ray system
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1600
Device Class:	Class II
Product Code:	IZI

2. Importer/Distributor Establishment:

Registration Number: 2240869

Siemens Medical Solutions, Inc.
51 Valley Stream Pkwy
Malvern, PA 19355

3. Manufacturing Facility:

Siemens AG
Wittelsbacherplatz 2
D-80333 Muenchen, Germany

4. Contact Person:

Mr. Rüdiger Körner
Manager Regulatory Submissions
Siemensstr.1; D-91301 Forchheim
Phone: +49 9191 18-9355
Fax: +49 9191 18-9782

5. Date of Preparation of Summary: October 15th, 2004

II. SAFETY AND EFFECTIVENESS INFORMATION SUPPORTING THE SUBSTANTIAL EQUIVALENCE DETERMINATION

1. General Safety and Effectiveness Concerns

The device labeling contains instructions for use and any necessary cautions and warnings, to provide for safe and effective use of the device.

Risk management is ensured via a hazard analysis, which is used to identify potential hazards. These potential hazards are controlled via software development, verification and validation testing. To minimize electrical, mechanical, and radiation hazards, Siemens adheres to recognized and established industry practice and standards.

2. Substantial Equivalence

The ***syngo InSpace 4D*** Software Package, addressed in this pre-market notification, is substantially equivalent to the following commercially available software package:

Manufacturer	Product	510(k)	Clearance date
Siemens	InSpace 3D	K011447	Aug. 03, 2001

(Remark: The current trade name of this software package is InSpace4D. This modification refers to the temporal dependence and has been separately documented.)

In summary, Siemens is of the opinion that *syngo InSpace 4D* Software Package does not introduce any new potential safety risks and is substantially equivalent to and performs as well as the predicate software components and the predicate device.

3. Intended Use

The *syngo InSpace 4D* software package is intended to assist the physician in skeletal and soft tissue imaging in addition to the originally approved indications.

4. Device Description

syngo InSpace 4D- Software Package is a self-contained image analysis software package. This real-time interactive evaluation in space and time for CT volume data sets provides the reconstruction of two-dimensional images into a three-dimensional image format.

InSpace can be used for the diagnosis of blood vessels on the basis of a CT Angiography dataset (CTA). For a CTA examination a contrast media (CM) is administered into the patient's blood vessels to enhance the contrast of the vessels in the CTA dataset, i.e. high values for the Hounsfield Unit (HU).

The goal is to visualize the blood vessels without other interfering anatomical structures.

The *syngo InSpace 4D* is developed to facilitate a precise diagnosis by removing bone structures from a CTA data set. It can also be used to extract and display selected bones, e.g. for the analysis of a fracture.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 3 2005

Siemens AG, Medical Solutions
% Mr. Stefan Preiss
Responsible Third Party Official
TÜV Product Service
1775 Old Highway 8
NEW BRIGHTON MN 55112-2487

Re: K043469
Trade/Device Name: "In Space 4D" with Bone Removal Feature
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: 90 JAK
Dated: January 13, 2005
Received: January 19, 2005

Dear Mr. Preiss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 3 **INDICATION FOR USE**

510(k) Number (if known): K043469

Device Name: ***InSpace 4D***

Indications for Use:

syngo InSpace 4D - Software Package is a self-contained image analysis software package. This real-time interactive evaluation in space and time for CT volume data sets provides the reconstruction of two-dimensional images into a three-dimensional image format.

InSpace can be used to assist the physician in the diagnosis of blood vessels on the basis of a CT Angiography dataset (CTA). For a CTA examination a contrast media (CM) is administered into the patient's blood vessels to enhance the contrast of the vessels in the CTA dataset, i.e. high values for the Hounsfield Unit (HU).

The goal is to visualize the blood vessels without other interfering anatomical structures.

The *syngo InSpace 4D* is developed to facilitate a precise diagnosis by removing bone structures from a CTA data set. It can be used in the same way for Non CTA datasets to remove bones or extract and display selected bones, e.g. for the analysis of a fracture.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) ~~AND~~/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K043469