AUG - 3 2001

Attachment 10

K011447

510(k) Summary
for the
Siemens In Space 3D Software Option

Submitted by:

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

10 May, 2001

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:**

Mr. Praveen Nadkarni
Phone: (732) 321-4950 Fax: (732) 321-4841

2. **Device Name and Classification:**

Trade Name:	In Space 3D Software Option
Classification Name:	Accessory to Angiographic X-Ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1600
Device Class:	Class I.I.
Product Code:	90JAA

3. **Substantial Equivalence:**

The In Space 3D software option is designed for three-dimensional evaluation of data acquired with a standard angiographic C-arm devices. The package is substantially equivalent to the following device:

Device Name	FDA Clearance Number	FDA Clearance Date
3D Angio Software Option	K984634	03/12/99
Siemens Siremobil Iso C 3D Imaging Option	K003266	10/18/00
Philips Integris 3D RA Option	K983877	12/21/98

4. **Device Description:**
The In Space 3D package is a x-ray imaging software option which allows the reconstruction of two-dimensional images acquired with a standard angiographic C-arm device into a three-dimensional image format.

5. **Intended Use of the Device:**
The In Space 3D package are intended to assist the physician in skeletal and soft tissue imaging in addition to the originally approved indications.

6. **Summary of Technological Characteristics of the Devices Compared to the Predicate:**
The Siemens In Space 3D software option and Philips Integris 3D-RA software allow construction of a three-dimensional model from two dimensional images acquired during rotational angiography.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Mr. Praveen Nadkarni
Technical Specialist
Siemens Medical Systems, Inc.
186 Wood Avenue South
ISELIN NJ 08830

AUG 23 2013

Re: K011447
Trade/Device Name: In Space 3D (Angiographic X-ray System Accessory)
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: May 10, 2001
Received: May 11, 2001

Dear Mr. Nadkarni:

This letter corrects our substantially equivalent letter of August 3, 2001.

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Attachment 11

Indications For Use

510(k) Number (if known): K011447
Device Name: In Space 3D Software Option

Indications For Use:

The In Space 3D package is a x-ray imaging software option which allows the reconstruction of two-dimensional images acquired with a standard angiographic C-arm device into a three-dimensional image format.

The In Space 3D package is intended for imaging both hard and soft tissues as well as other internal body structures(eg. Lesions, Stent implants) for diagnosis, surgical planning, interventional procedures and treatment follow-up.

As with the FDA cleared 3D Angio software package(K984634), this software package will also assist the physician in diagnosis and treatment of vessel malformations(i.e. Aneurysms, AVMs and Stenoses).

(Please do not write below this line - continue on another page if needed)

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

David C. Seigerman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K011447

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