NOV - 4 2005

K053024

Attachment 8

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:	***syngo Neuro DSA CT***
Classification Name:	Accessory to Computed Tomography System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750
Device Class:	Class II
Product Code:	90 JAK

2. Importer/Distributor Establishment:

Registration Number: 2240869

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

3. Manufacturing Facility:

Siemens AG
Medical Solutions
Henkestrasse 127

D-91052 ' angen, 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: August 26th 2005

II. SAFETY AND EFFECTIVENESS INFORMATION SUPPORTING THE SUBSTANTIAL EQUIVALENCE DETERMINATION

6. 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.

7. Substantial Equivalence:

The ***syngo Neuro DSA CT*** software package that is addressed in this premarket notification, is substantially equivalent to the following commercially available software package:

Manufacturer	Product	510(k)	Clearance date
1. Siemens	InSpace 4D	K043469	02/03/2005
2. Siemens	Leonardo	K040970	07/08/2004

8. Device Description and Intended Use:

syngo Neuro DSA CT is a dedicated post-processing application which allows removing bone structures from CT Angiography (CTA) data sets of the cerebral vasculature. Bone removal is based on a bone mask created from an additional non enhanced CT (NECT) scan that was three-dimensionally registered to the CTA data set.

Syngo Neuro DSA CT facilitates the diagnosis of the cerebral vasculature by removing interfering bone structures from CTA data. This particularly helps to delineate aneurysms and other vascular diseases in the area of the skull base.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 4 2005

Siemens AG
% Stefan Preiss
Responsible Third Party Official
TUV America, Inc.
1775 Old Highway 8
NEW BRIGHTON MN 55112-1891

Re.: K053024
Trade/Device Name: Syngo Neuro DSA CT
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: October 13, 2005
Received: October 21, 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/industry/support/index.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

Attachment 2

Indication for use

510(k) Number (if known): K053024

Device Name: ***syngo Neuro DSA CT***

syngo Neuro DSA CT is a dedicated post-processing application which allows removing bone structures from CT Angiography (CTA) data sets of the cerebral vasculature. Bone removal is based on a bone mask created from an additional non enhanced CT (NECT) scan that was three-dimensionally registered to the CTA data set.

Syngo Neuro DSA CT facilitates the diagnosis of the cerebral vasculature by removing interfering bone structures from CTA data. This particularly helps to delineate aneurysms and other vascular diseases in the area of the skull base.

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

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

Prescription Use ☒ OR Over-The-Counter Use ☐

(Per 21 CFR §801.109)

Carolyn C. Neuland

(Division Sign-Off)

for Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K053024