K014113

JUN 14 2002

## 510(K) SUMMARY

Submitted by:
Siemens Medical Solutions USA, Inc.
186 Wood Avenue South
Iselin, NJ 08830

December 12, 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**

Ms. Sandra Robinson
Phone: (732) 321-3243 Fax: (732) 321-4841

**2. Device Name and Classification**

| | |
|---|---|
| Trade Name: | EndoMap |
| Classification Name: | Template for Clinical Use |
| Classification Panel: | Radiology |
| CFR Section: | 21 CFR § 888.4800 |
| Device Class: | Class II, though it is defined as class I, exempt |
| Device Code: | HWT |

**3. Intended Use**

The EndoMap package is an x-ray imaging system software option, which allows the planning of orthopedic surgeries on a workstation. The software is intended to read in diagnostic images (e.g. digitized x-rays) for use with a database of orthopedic implant geometries and dimensions. This provides a constructed image of this data, to use in conjunction with the EndoMap software to overlay the constructed images to aid surgeons in their planning of orthopedic surgeries.

**4. Substantial Equivalence**

The EndoMap is substantially equivalent to the current, commercially available BrainLabs' VectorVision Hip, and BrainLabs' VectorVision Knee.

| *Device Name* | *FDA Clearance Number* | *FDA Clearance Date* |
|---|---|---|
| VectorVision Knee | K010612 | 09/06/2001 |
| VectorVision Hip | K010602 | 09/12/2001 |

Information that substantiates this claim of equivalence is provided throughout this 510(k) submission and specific equivalence information is provided in Attachment 5.

**5. Device Description**

The EndoMap System is a x-ray imaging software option, which allows the planning of orthopedic surgeries on several Siemens workstations such as the LEONARDO, the *syngo*® Multimodality Workstation and the Magic View 300. The Leonardo Workstation was described in the 510(k) premarket notification, K992073, which received FDA clearance on Sept. 09, 1999. The *syngo*® Multimodality Workstation K010938 received FDA clearance on June 26, 2001. The EndoMap program enables exact adaptation of the prosthesis to the existing anatomic conditions based on digital images of the pelvis and the leg skeletal structure. This is accomplished using various help functions such as determination of the rotation center and the rotation of the pelvis, medialization/ lateralization, leg length correction, reflection via the symmetric axis of the body, biomechanical evaluation of the hip geometry and coxometry (analysis of the hip values). The planning data can be saved to the database of the LEONARDO or other workstations and output to a laser or paper printer.

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6. **Summary of Technological Characteristics of the Principal Device as Compared with the Predicate Device**

The Siemens EndoMap software package and the BrainLabs' VectorVision Hip, and BrainLabs' VectorVision Knee software packages allows the planning of orthopedic surgeries on a workstation, which reads in diagnostic images (e.g. digitized x-rays) for use with a database of orthopedic implant geometries and dimensions.

7. **General Safety and Effectiveness Concerns**

Instructions for use are included within the device labeling and the information provided will enable the trained healthcare professional to operate the device in a safe and effective manner. Furthermore the operators are health care professionals familiar with and responsible for the planning of orthopedic surgeries to be performed.

8. **Summary of Substantial Equivalence**

In the opinion of Siemens Medical Solutions USA, Inc., the functional specifications and the substantial equivalence comparison matrix proves that the EndoMap Software is substantially equivalent to the BrainLab AG predicate VectorVision Knee and VectorVision Hip software.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Sandra Robinson
Siemens Medical Solutions, Inc.
186 Wood Avenue South
Iselin, NJ 08830

Re: K014113
Trade/Device Name: Endomap
Regulation Number: 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: March 15, 2002
Received: March 19, 2002

Dear Ms. Robinson :

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 (PMA), 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## INDICATIONS FOR USE

**510(k) Number (if known):** K014113

**Device Name:** EndoMap

**Indications for Use:**
The EndoMap package is an x-ray imaging system software option, which allows the planning of orthopedic surgeries on a workstation. The software is intended to read in diagnostic images (e.g. digitized x-rays) for use with a database of orthopedic implant geometries and dimensions. This provides a constructed image of this data, to use in conjunction with the EndoMap software to overlay the constructed images to aid surgeons in their planning of orthopedic surgeries.

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

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

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

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