K071179

JUN 1 8 2007

510(k) Summary
OR Head Holder

Date of Summary Preparation: April 20, 2007

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

1. General Information

Importer/Distributor
Name and Address
Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway, E-50
Malvern, PA 19355

Establishment Registration Number
2240869

Manufacturing Site
Name and Address
Noras Röntgen- und Medizintechnik GmbH
Leibnizstrasse 4
97204 Höchberg
Germany

Establishment Registration Number
Establishment Registration 3004929307

Owner/Operator 9071737

2. Contact Person

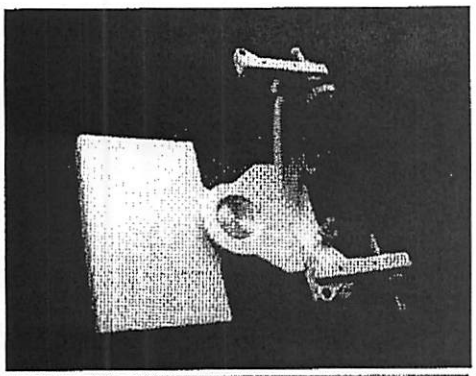
Judy Campbell
Siemens Medical Solutions, Inc.
51 Valley Stream Parkway, E-50
Malvern, PA 19355
Telephone: (610) 448-4918
Fax: (610) 448-1787
Email Address: judith.campbell@siemens.com

3. Device Name and Classification

Trade Name:	**OR Head Holder**
Common Name:	**OR Head Holder**
Classification Name:	Magnetic Resonance Diagnostic Device
Classification Panel:	Neurology
CFR Number:	21 CFR § 882.446
Device Class:	II
Product Code:	HBL

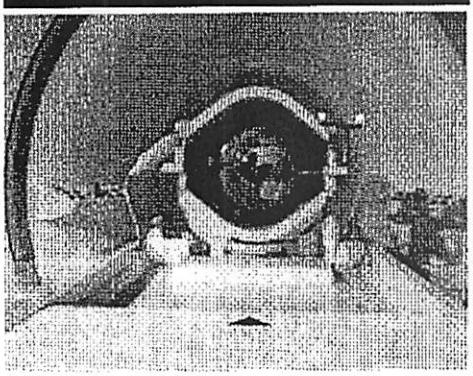
4. Device Description

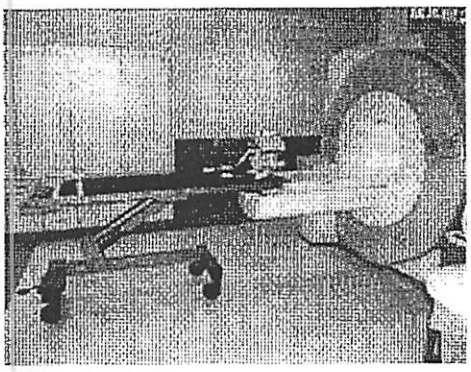
The OR Head Holder is a fixation unit for the human head before, during and after an intervention at the human brain. The head holder will come with two versions of table adapters, depending on the OR table top used.
The Noras Part Numbers are: SI7000 for use with the Symphony, and Sonata Table top and the Miyabi transport system; and Part Number SI7300 for use with the table top for Espree or TIM Trio.



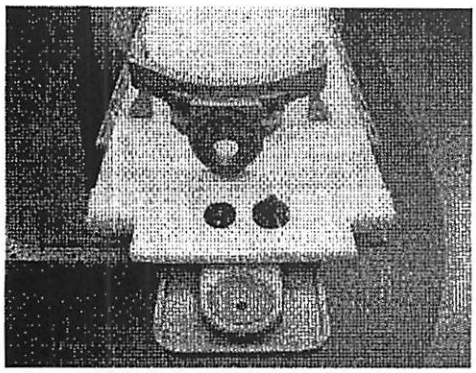
The picture on the left shows the OR Head holder SI7000 with the rectangular base plate (left) to fix the head holder to the OR table top or Miyabi shell.

On the right there is the C-Arc visible with the screws to fix the skull.



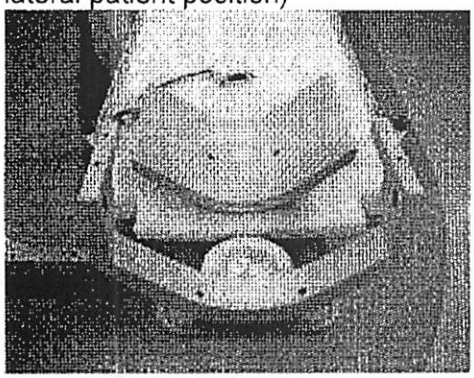


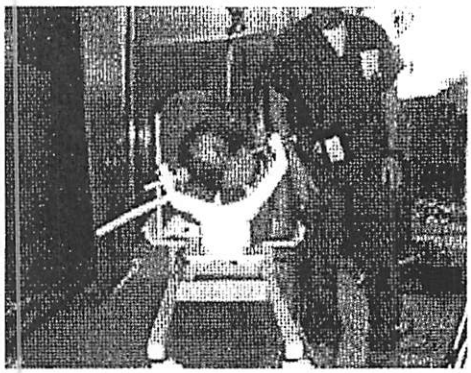
The pictures above show the OR Head holder SI7000 (right mounted on the table top for Magnetom Sonata and Symphony, left mounted on the Miyabi transport system with optional OR Head Coil and reflectors for navigation system.



The picture on the left shows the OR Head holder SI7300 and the OR table top for Siemens Magnetom Espree and Tim Trio. The big base plate with the lower part of the hemisphere joint is implemented into the OR table top.

The pictures below show the OR Head holder SI7300 mounted on the OR table top for Siemens Magnetom Espree or Tim Trio. (left prone and supine position, right lateral patient position)





The head holder always remains the same, but the package differs only in the table connection.

5. Intended Use

The intended use of the Noras OR Head Holder is the fixation of the human skull just before, during and at the end of the intervention in the operating room. The head holder enables prone, supine and lateral patient positioning.

The Noras OR Head Coil 1.5T(K060758) can be adopted to the OR Head Holder in conjunction with a Siemens Magnetom System 1.5T to provide MR images before, during and at the end of the intervention.
The head holder can be adjusted from adult use down to use for a new born child.

6. Substantial Equivalence

Noras and Siemens believe that, within the meaning of the Safe Medical Devices Act of 1990, the OR Head Holder for Magnetom Systems is substantially equivalent to the following Neurosurgical OR Head Holder:

Device Name	Premarket Notification	Clearance Date
SIEMENS Neurosurgical OR Head Holder Catalog #7548204	K012495	October 31, 2001

7. Summary of Technological Characteristics of the Principal Device as Compared with the predicate Device

Both Neurosurgical OR Head Holders are designed to fix a human skull in the OR environment. Both units have been designed to work directly in the magnetic field of an MR.

8. General Safety and Effectiveness Concerns

Device Description

The OR Head Holder is a fixation unit for the human skull. It can be mounted on the Symphony/Sonata/Espree/Trio table top or the Miyabi Shell.

The OR Head holder provides the possibility to adopt the 1.5T Noras OR Head Coil and in conjunction with a 1.5T Magnetic Resonance Scanner, the MR examination of the human brain just before, during and at the end of brain surgery in the operating room.

9. Conclusion as to Substantial Equivalence

Noras and Siemens believe that, within the definition of the Safe Medical Device Act of 1990, the Noras OR head holder SI7000 or SI7300 is substantially equivalent to the predicate device listed above.
Both systems are used to stabilize the head of the patient during the entire neurosurgical procedure in the OR environment.

Hubert Noras
President

April 20, 2007

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Ms. Judith Campbell
Regulatory Technical Specialist
Siemens Medical Solutions, Inc.
51 Valley Stream Parkway, E-50
MALVERN PA 19355

March 30, 2014

Re: K071179
Trade/Device Name: Noras OR Head Holder
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS, HBL
Dated: April 24, 2007
Received: April 27, 2007

Dear Ms. Campbell:

This letter corrects our substantially equivalent letter of June 13, 2007.

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact 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/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara For

Janine M. Morris
Director, Division of Radiological Health
Office of *In Vitro* Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071179

Device Name:

Noras OR Head Holder

Indications for Use:

The intended use of the Noras OR Head Holder, in conjunction with a Magnetic Resonance Scanner, is to stabilize patient's head during neurosurgical procedures.

Used in conjunction with Siemens MAGNETOM Systems and the Noras OR Head Coil, it is indicated for use together with a navigation system.

Special Accessories are available for use with the head holder for awake craniotomies, pediatric patients and minimally invasive interventions.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K071179

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