MAR 2 3 2012

510(k) Summary

K112469

510(k) Number:

Device Trade Name:	General purpose localizers and adapters – new accessories for SonoWand Invite System
Device Common Name:	Diagnostic ultrasound neuronavigation intraoperative imaging system
Device Regulation Name:	Sterotaxic instrument (21 CFR 882.4560, Class II, Code: HAW,IYN)
Submitter:	SONOWAND AS Nedre Ila 39 7018 Trondheim NORWAY Phone number: 0047 73805900
Contact Information:	Constance G. Bundy C. G. Bundy Associates, Inc. 435 Rice Creek Terrace NE Fridley, MN 55432 763-574-1976 Fax: 763-571-2437 cgbundy@live.com
Submission Date:	August 24, 2011

Equivalent Device Identification:
The purpose of this submission is to add additional accessories to the SonoWand Invite System. The additional accessories are general purpose localizers with adapters. These accessories are equivalent in function and intended use to the Navigator tool which was cleared in the original 510(k), K083597.

Device Description:
The 510(k) cleared SonoWand Invite System is a neuronavigation system with intraoperative imaging capabilities. An ultrasound scanner is physically integrated with a neuronavigation system in a single rack of equipment.
SonoWand Invite can be used as a conventional neuronavigation system based on preoperative MR or CT-images, or as a stand-alone ultrasound scanner for real-time 2D imaging or as a combined system where 3D ultrasound data can be transferred to the navigation system for direct navigation.

SonoWand Invite has basically two functionalities. It supports the surgeon by showing the position of tools or pointers relative to MR, CT or Ultrasound images. It also makes it possible for the surgeon to acquire ultrasound images during operation, which can be compared with other images (such as MR or CT) and can be used for supporting the surgeon by showing the position of tools and pointers. The control is primarily by a graphical touch screen. The secondary control is by a footswitch.
The new accessories, General purpose localizers with adapters, shall be used to attach surgical tools manufactured by other vendors. SonoWand Invite will then display position and orientation of the tools in the medical images on the screen in the same way as the previous 510(k) cleared Navigator tool.

The localizers with adapters are designed to fit surgical tools normally used in the operating room.

There are no changes to the Intended use, function or technological aspects including software of the SonoWand Invite. The additional accessories are being added to increase usability of the SonoWand Invite system.

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Intended Use:
The Sonowand Invite system is intended for use as a tool to aid intraoperative ultrasound imaging and image guided surgery during neurosurgery. It is also intended for use as a standard neuronavigation system and as a stand-alone ultrasound scanner.
The intended use of a localizer is to enable navigation by showing the position of surgical instruments or pointers relative to MR, CT or Ultrasound images
The General purpose localizers with adapters are intended to be used to attach surgical tools manufactured by other vendors. SonoWand Invite System will display position and orientation of the tools in the medical images on the screen.

Comparison Chart:

Element of Comparison	**Subject**		**Predicate Device**		**Comment**
	SonoWand Invite new accessories		**K083597** SonoWand Invite accessories		
Common name	General purpose localizers, small and large	User tool adapters (*) Bracket & Clamp adapter	Navigator, intraoperative	Probe localizers for variable size ultrasound probes	
Pictures					Accessories are biocompatible and sterilizable.
					
Intended use of accessories	The intended use of a localizer is to enable navigation by showing the position of surgical instruments or pointers relative to MR, CT or Ultrasound images	The adapter is intended to connect the general purpose localizer with a variety of surgical instruments	The intended use of a localizer is to enable navigation by showing the position of the Navigator (pointer) relative to MR, CT or Ultrasound images	The intended use of a probe localizer is to enable accurate imaging during surgery by tracking the probes location relative to the patient.	No changes to intended use or the functionality of SonoWand Invite(**). The adapted surgical instruments are given the same functionality as the Navigator (pointer). Connecting a localizer to the device does not affect the intended use of the connected device.
Materials	316 L Stainless steel, 6082 Aluminium DLC Coating	316 L Stainless steel, Plastic Radel PPSU (PEEK)	316 L Stainless steel, 6082 Aluminium DLC Coating	316 L Stainless steel, 6082 Aluminium DLC Coating	New material; Plastic Radel PPSU (PEEK) are widely used for surgical instruments. The material is in compliance with both United States Pharmacopeias (USP) and ISO 10993-1 guideline requirements for Biocompatibility Testing of Materials.

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(*) Images show adapters attached to localizers

(**) SonoWand Invite has basically two functionalities. It supports the surgeon by showing the position of tools or pointers relative to MR, CT or Ultrasound images. It also makes it possible for the surgeon to acquire ultrasound images during operation, which can be compared with other images (such as MR or CT) and can be used for supporting the surgeon by showing the position of tools and pointers.

Intended use:
There are no changes to the Intended use of the SonoWand Invite.
The additional accessories (localizers and adapters) will facilitate the commonly used surgical instruments with the same functionality as the Navigator (pointer).
Connecting a localizer to the device does not affect the intended use of the connected device.

Technological and performance characteristics:
Technological characteristics of the localizers and adapters, including device design and performance, are substantially equivalent to the accessories of the predicate device SonoWand Invite, K083597.

Summary of Testing:
The new localizers and adapters have been tested to and comply with all applicable cleaning and sterilization standards.
The devices subject to this submission do not contain software. The software module in the cleared SonoWand Invite System that supports the function of the subject devices has been tested to and complies with requirements.
The Localizers have been tested to and comply with requirements of the SonoWand Invite System Test.
The Adapters were tested for fit, calibration and accuracy.
Results of the tests performed show the General purpose localizers and adapters are as safe and effective as the accessories of the predicate device.

Conclusion:
The conclusion drawn from the testing is that the localizers and adapters can be used for supporting the surgeon by showing the position of surgical tools.
Connecting a localizer to the device does not affect the intended use of the connected device.
Results of the tests performed show the new accessories (localizers and adapters) to SonoWand Invite are as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Sonowand AS
% C.G. Bundy Associates, Inc.
Ms. Constance G. Bundy
435 Rice Creek Terrace NE
Fridley, Minnesota 55432

MAR 2 3 2012

Re: K112469
Trade/Device Name: General purpose localizers and adapters – new accessories for SonoWand Invite System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW, IYN
Dated: March 14, 2012
Received: March 20, 2012

Dear Ms. Bundy:

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

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SONOWAND AS
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NORWAY

sono wand™

Indications for Use

510(k) Number (if known): K112469

Device Name: General purpose localizers and adapters – new accessories for SonoWand Invite System

Indications For Use:

The Sonowand Invite System is intended for use as a tool to aid intraoperative ultrasound imaging and image guided surgery during neurosurgery. It is also intended for use as a standard neuronavigation system and as a stand-alone ultrasound scanner.

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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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden for max

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112469