K102967

We are **smith&nephew**

Submitted by:	Smith & Nephew, Inc. Orthopaedic Division 1450 East Brooks Road Memphis, Tennessee 38116
Date of Summary:	October 4, 2010
Contact Person and Address:	Shereen Myers, Regulatory Affairs Specialist T (901) 399-6325 F (901) 566-7075
Name of Device:	Smith & Nephew, Inc. SURESHOT® Distal Targeting System V2.0.2
Common Name:	Computer Assisted Surgery System
Device Classification Name and Reference:	21 CFR 882.4560 Stereotaxic Instrument – Class II
Device Class:	Class II
Panel Code:	Neurology/84
Product Code:	OLO

NOV - 4 2010

Device Description

Subject of this Special Premarket Notification are modifications to existing SURESHOT® Targeting System software. The SURESHOT® Targeting System is a computer controlled electromagnetic tracking system. It assists the surgeon in locating and positioning screws in an intramedullary nail implant during orthopedic trauma surgery. The link between the sterile surgical area (patient) and the instrument system is provided through an electromagnetic tracking system. Electromagnetic spatial measurement systems determine the location of instruments that are embedded with sensor coils. When the sensor-embedded instrument is placed inside controlled, varying magnetic fields, voltages are induced in the sensor coils. These induced voltages are used by the measurement system to calculate a 3D virtual position of the instrument. Because the magnetic fields are of a low field strength and can safely pass through human tissue, location measurement of an object is possible without the line-of-sight constraints of an optical spatial measurement system that requires a camera.

The SURESHOT® Targeting System software is intended to be used with existing Smith & Nephew platform, instruments and implants. The software devices subject of this premarket notification are the following:

- SURESHOT® Distal Targeting System Software V2.0.2
- Trauma Launcher V1.0.1

Technological Characteristics

Software verification and validation testing was completed in line with FDA's guidance document entitled, "General Principles of Software Validation; Final Guidance for Industry and FDA Staff," dated January 11, 2002. A review of this testing has demonstrated that there are no new issues related to the safety and effectiveness of the subject device and the software will perform as intended. Clinical data was not needed to support the safety and effectiveness of the subject device.

Intended Use

The Smith & Nephew SURESHOT® Targeting System is intended to be an intraoperative image guided localization system. It is a computer assisted orthopedic surgery tool to aid the surgeon with drill positioning for screws during intramedullary nail implantation. It provides information to the surgeon that is used to place surgical instruments during surgery utilizing intraoperatively obtained electromagnetic tracking data. The Smith & Nephew SURESHOT® Targeting System is indicated for long bone fractures treated with intramedullary nails in which the use of stereotactic surgery may be appropriate.

Substantial Equivalence Information

The substantial equivalence of the SURESHOT® Targeting System software is based on its similarities in indications for use, design features, and operational principles to the predicate systems listed in the table below.

Table 1: Substantially Equivalent Predicate Systems

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew	Smith & Nephew PiGalileo Screw Targeting System V1.1	K092497	09/11/09
Smith & Nephew	Smith & Nephew SURESHOT® Distal Targeting System v.2.0	K100107	02/23/10

Conclusion

As previously noted, this Special 510(k) Premarket Notification is being submitted to request clearance for the SURESHOT® Targeting System software modifications. Based on the similarities to the predicate components and a review of the validation testing performed, the device is substantially equivalent to above predicate systems.

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

Smith & Nephew, Inc.
Orthopaedic Division
% Ms. Shereen Myers
Regulatory Affairs Specialist
1450 East Brooks Road
Memphis, Tennessee 38116

NOV - 4 2010

Re: K102967
Trade/Device Name: SURESHOT Distal Targeting System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OLO
Dated: October 04, 2010
Received: October 05, 2010

Dear Ms. Myers:

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 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,

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

Enclosure

Premarket Notification
Indications for Use Statement

NOV - 4 2010

510(k) Number (if known): _____

Device Name: SURESHOT Targeting System V2.0.2

Indications for Use:
The Smith & Nephew SURESHOT Targeting System is intended to be an intraoperative image guided localization system. It is a computer assisted orthopedic surgery tool to aid the surgeon with drill positioning for screws during intramedullary nail implantation. It provides information to the surgeon that is used to place surgical instruments during surgery utilizing intraoperatively obtained electromagnetic tracking data. The Smith & Nephew SURESHOT Targeting System is indicated for long bone fractures treated with intramedullary nails in which the use of stereotactic surgery may be appropriate.

Prescription Use		AND/OR	Over-The-Counter Use	
(Part 21 CFR 801 Subpart D)	X		(21 CFR 807 Subpart C)	

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K102967