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

May 3, 2017

Smith & Nephew, Inc.
Allison Chan
Regulatory Affairs Specialist II
1450 Brooks Rd
Memphis, Tennessee 38116

Re: K170977
Trade/Device Name: SURESHOT Distal Targeting System V4.0 Trauma Interface
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: March 31, 2017
Received: April 3, 2017

Dear Allison Chan:

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

Mark N. Melkerson -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170977

Device Name
SURESHOT™ Distal Targeting System V4.0

Indications for Use *(Describe)*
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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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We are smith&nephew

Submitted by:	Smith & Nephew, Inc. Advanced Surgical Devices Division 1450 East Brooks Road Memphis, Tennessee 38116
Date of Summary:	May 1, 2017
Contact Person and Address:	Allison Chan Regulatory Affairs Specialist II T 901-399-1098 F 901-566-7022
Name of Device:	Smith & Nephew, Inc. SURESHOT™ Distal Targeting System V4.0
Common Name:	Computer Assisted Surgery System
Device Classification Name and Reference:	21 CFR 882.4560 Stereotaxic Instrument
Device Class:	Class II
Panel Code:	Neurology/84
Product Code:	OLO

Device Description

Subject of this premarket notification are modifications to the SURESHOT™ Distal Targeting System trauma interface which include reduced overall size and weight, addition of HDMI video output, removed VESA Mounting Post, improved screen resolution and reduced screen size compared to the previous design of the trauma interface (K100107). The second generation trauma interface uses the SURESHOT Targeting System V4.0 software (K170280).

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 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™ Distal Targeting System trauma interface is intended to be used with existing Smith & Nephew software, targeter, instruments and implants. No new instruments or implants are being cleared via this premarket notification.

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.

Summary of Pre-Clinical Testing

Electromagnetic compatibility and electrical safety validation testing has been conducted on the SURESHOT™ Distal Targeting System. The subject device utilizes the same platform and tracking technology as previously cleared in K100107. The electromagnetic capability and electrical safety testing that was conducted includes.

- IEC 60601-1: 2005 + A1:2012 Medical Electrical Equipment Part 1: General Requirements for Safety.
- IEC 60601-1-2:2007 Class A for Emissions, Immunity for Non Life Supporting Equipment

Results of the electromagnetic compatibility and electrical safety validation testing demonstrate the device is found to meet the application performance requirements to those standards.

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. The software for this device was considered to be a “moderate” level of concern.

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 as compared to the predicate. Clinical data was not needed to support the safety and effectiveness of the subject device.

Comparison to Technological Characteristics with the Predicate Device

Device comparisons described in this premarket notification demonstrated that the proposed SURESHOT™ Targeting System is equivalent to the legally marketed predicate devices cleared in the below table with regard to intended use, indications for use, and performance characteristics.

The subject devices feature characteristics as previously cleared in K100107 with the primary differences being the reduced size and weight. All software features remain the same as those in K170280.

Substantial Equivalence Information

The substantial equivalence of the SURESHOT™ Targeting System trauma interface is based on its similarities in indications for use, design features, sterilization methods and operational principles to the predicate systems listed in the following table.

Table 5.1: Substantially Equivalent Predicate Systems to SURESHOT™ Targeting System

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew	Smith & Nephew SURESHOT™ Distal Targeting System V.2.0	K100107	February 23, 2010

A comparison of the subject device to the predicate device is described in the following table.

Design Aspect Reviewed	**SURESHOT™ Distal Targeting System V4.0**	**SURESHOT™ Distal Targeting System V.2.0**
510(k) Number	Subject device	K100107
Manufacturer	Smith & Nephew	Smith & Nephew
Similar 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.	
Intended Use	Intraoperative image guided localization system	
Instrumentation	Used to assist surgeon in placing nail implants and for specific use with the distal targeting software	
Similar Sterilization	Y	Y
Similar Packaging	Y	Y
Similar Materials	Y	Y
Overall Dimensions Trauma Interface	31cm x 26cm x 13cm	40cm x 38cm x 20cm
Overall Weight Trauma Interface	3.5kg	9kg
System Design	Electromagnetic tracking System, sensor coils, console (includes PC, control unit, and display monitor), instruments	Electromagnetic tracking System, sensor coils, console (includes PC, control unit, and display monitor), instruments
Tracking System	Aurora, Northern Digital Inc.	Aurora, Northern Digital Inc.
Software Requirements Hardware	• Microprocessor : Celeron n2930 (1.8 Ghz) • Memory Devices: 4GB	• Microprocessors: P4 Mobile; P4, P3 (800mhz min) • Memory Devices : 512 MB RAM

	• Sensors : Touch Screen, On Screen keyboard • Energy Sources: 110V-240V • Safety Features: 3.15 Amp Fuse	(minimum) • Sensors: Keyboard, Mouse, Touch Screen, Screen Keyboard • Energy Sources: 110V-240V • Safety Features: 3.15 Amp Fuse
Workstation/ PC	Celeron n2930; Windows Embedded 8 or higher	Intel Pentium Panel PC with touchscreen; Windows XP embedded or higher
VESA Mounting Posts	N/A	VESA Mounting Posts present on rear panel on trauma interface
HDMI Output	Addition of HDMI Connection	N/A
VGA Output Resolution	1280 x800	1024 x 768
Screen Size	10 inch monitor	15 inch monitor
Software Compatibility	SURSHOT Distal Targeting System V4.0 software (K170280)	SURESHOT Distal Targeting System V4.0(K170280) SURESHOT Distal Targeting System V3.0 (K130748) SURESHOT Distal Targeting System V2.1 (K102967) SURESHOT Distal Targeting System V2.0 (K100107)

Conclusion

The SURESHOT™ Distal Targeting System V4.0 trauma interface is substantially equivalent to the existing SURESHOT™ Distal Targeting System trauma interface cleared in K100107 in that the indications for use for these devices are identical and the core technological principles for these devices are also equivalent.