DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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April 28, 2017

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

Re: K170280
Trade/Device Name: Smith & Nephew SURESHOT™ Distal Targeting System V4.0
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OLO
Dated: January 27, 2017
Received: January 30, 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,

Lori A. Wiggins -S

for
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)*

K170280

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.

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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:	April 24, 2017
Contact Person and Address:	Allison Chan Regulatory Affairs Specialist II T 901-399-1098
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 888.4560 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™ Targeting System to include software updates (V4.0) to include the ability to target for the TRIGEN META-TAN Nail (previously cleared in K092748), the ability for on screen rotation using the SURESHOT™ Targeter, additional languages of the graphical user interface (for international users), updates to the graphical user interface, and updates to the Launcher program

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 software is intended to be used with existing Smith & Nephew platform, 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.

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 K130748 with the primary differences being additional software features which include the ability to target for the TRIGEN META-TAN Nail (previously cleared in K092748), the ability for on screen rotation using the SURESHOT™ Targeter, additional languages of the graphical user interface (for international users), updates to the graphical user interface, and updates to the Launcher program

Summary of Pre-Clinical Testing
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. Preclinical testing included the following tests:

- 12.102 Software Validation and Verification Report
- 12.201 Deployment Distal Targeting Software
- 12.301 Workflow and System Settings
- 12.302 Tool Connections
- 12.303 Sleeve Selection
- 12.304 Implant Selection
- 12.305 Drilling Screen
- 12.306 Hardware Failure
- 12.307 Drill Depth Measurement
- 12.308 Targeting Calculations META
- 12.309 Targeting Calculations TAN/FAN
- 12.310 Targeting Calculations Humeral
- 12.311 Targeting Calculations Field Check
- 12.312 Targeting Calculations META-TAN
- 12.313 Translations Chinese
- 12.314 Translations English
- 12.315 Translations French
- 12.316 Translations German

- 12.317 Translations Italian
- 12.318 Translations Japanese
- 12.319 Translation Portuguese
- 12.320 Translation Finnish
- 12.321 Translation Spanish
- 12.322 Nail Rotation
- 12.323 View Selection
- 12.401 Customer Validation
- 12.402 Regression Test

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.

Substantial Equivalence Information

The substantial equivalence of the SURESHOT™ Targeting System software 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.3.0	K130748	August 4, 2013
Smith & Nephew	Smith & Nephew SURESHOT™ Distal Targeting system V.2.1	K110240	April 4, 2011
Smith & Nephew	Smith & Nephew SURESHOT™ Distal Targeting System V.2.0.2	K102967	November 4, 2010
Smith & Nephew	Smith & Nephew SURESHOT™ Distal Targeting System V.2.0	K100107	February 23, 2010
Smith & Nephew	Smith & Nephew PiGalileo Screw Targeting System V1.1	K092497	September 11, 2009

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

Design Aspect Reviewed	SURESHOT™ Distal Targeting System v.4.0	SURESHOT™ Distal Targeting System v.3.0 – *primary predicate*	SURESHOT™ Distal Targeting System v.2.1	SURESHOT Distal Targeting System v.2.0.2	SURESHOT Distal Targeting System v.2.0	PiGalileo Screw Targeting System V1.1
510(k) Number	Subject Device	K130748	K110240	K102967	K100107	K092497
Manufacturer	Smith & Nephew	Smith & Nephew	Smith & Nephew	Smith & Nephew	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	Y	Y	Y	Y
Similar Packaging?	Y	Y	Y	Y	Y	Y
Similar Materials?	Y	Y	Y	Y	Y	Y
Software Design	Provides information to the surgeon that is used to place surgical instruments during surgery utilizing intraoperatively obtained electromagnetic tracking data.					
	Addition of ability to target for TRIGEN META-TAN Nail	*Addition of drill depth measurement, Trauma*	*Addition of humeral nail application.*			

Design Aspect Reviewed	SURESHOT™ Distal Targeting System v.4.0	SURESHOT™ Distal Targeting System v.3.0 – *primary predicate*	SURESHOT™ Distal Targeting System v.2.1	SURESHOT Distal Targeting System v.2.0.2	SURESHOT Distal Targeting System v.2.0	PiGalileo Screw Targeting System V1.1
	(K092748), updates to Trauma Launcher program, ability of on screen image rotation using targeter, additional languages for the graphical user interface, updates to graphical user interface.	*Launcher updates, GUI updates, new instrument and Japan Nail application.*				

Conclusion

The SURESHOT™ Distal Targeting System V4.0 is substantially equivalent to the existing SURESHOT Distal Targeting System V3.0 cleared in K130748 in that the indications for use for these devices are identical and the core technological principals for these devices are also equivalent.