Smith & Nephew, Inc.
Brad Sheals
Regulatory Affairs Manager
7135 Goodlett Farms Parkway
Cordova, Tennessee 38016

April 24, 2018

Re: K180277
Trade/Device Name: Smith & Nephew SURESHOT Distal Targeting System V4.0 Targeter
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: March 23, 2018
Received: March 26, 2018

Dear Brad Sheals:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180277

Device Name
Smith & Nephew 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 20, 2018
Contact Person and Address:	Brad Sheals Regulatory Affairs Manager T 901-399-6897
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 V4.0- targeter which has been designed with a reduced size and weight compared to the previous design of the targeter (K092497). The SURESHOT Targeting system targeter is intended to be used the SURESHOT trauma interfaces (K170977, K100107) and software V4.0 (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 V4.0 targeter is intended to be used with existing Smith & Nephew software, trauma interface, 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 K092497 with the primary differences being the reduced size and weight.

Summary of Pre-Clinical Testing
Electromagnetic compatibility and electrical safety validation testing has been conducted on the SURESHOT™ Distal Targeting System. The SURESHOT Distal Targeting System V4.0 targeter is used with the trauma interface. The subject device generates the same electromagnetic tracking technology as the existing targeter cleared in PiGalileo Screw Targeting System V1.1. The electromagnetic capability and electrical safety testing that was conducted includes.

- IEC 606061-1-2:2007 Class A for Emissions, Immunity for Non Life Supporting Equipment
- IEC 60601-1: 2005 + A1 :2012 Medical Electrical Equipment Part 1: General Requirements for Safety.

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. 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 V4.0 - targeter 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	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 V4.0-Targeter**	**PiGalileo Screw Targeting System V1.1**
510(k) Number	Subject device	K092497
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.	The Smith & Nephew PiGalileo Screw 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 PiGalileo Screw Targeting System V1.1 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 Materialsf the	Y	Y
Similar Design	Y	Y
Overall Weight Targeter	~750g	~1kg

Design Aspect Reviewed	SURESHOT™ Distal Targeting System V4.0-Targeter	PiGalileo Screw Targeting System V1.1
Software Compatibility	SURSHOT Distal Targeting System V4.0 software (K170280)	PiGalileo Screw Targeting System V1.1 (K092497)

Conclusion

The SURESHOT™ Distal Targeting System V4.0 targeter is substantially equivalent to the existing PiGalileo Screw Targeting System V1.1 handheld field generator (targeter) cleared in K092497 in that the indications for use for these devices are identical and the core technological principals for these devices are also equivalent.