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

August 21, 2014

Smith & Nephew, Inc.
Ms. Jenny Waldrip
Regulatory Affairs Specialist
7135 Goodlett Farms Parkway
Cordova, Tennessee 38016

Re: K141585
Trade/Device Name: Smith & Nephew Disposable Fin Punch
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemororotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH, MBH
Dated: July 1, 2014
Received: July 2, 2014

Dear Ms. Jenny Waldrip:

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" (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,

Lori A. Wiggins -S

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

Enclosure

Premarket Notification
Indications for Use Statement

510(k) Number (if known): K141585

Device Name: Disposable Fin Punch

Indications for Use:

Smith & Nephew Disposable Fin Punch is an accessory device and is intended to be used to assist in the implantation of Smith & Nephew Total Knee Systems including Legion and Genesis II Knee Systems and their cleared Indications for Use.

Indications for Total Knee Replacement

1. Rheumatoid arthritis.
2. Post-traumatic arthritis, osteoarthritis, or degenerative arthritis in older patients whose age, weight, and activity level are compatible with an adequate long-term result.
3. Failed osteotomies, unicompartmental replacement, or total knee replacement.
4. Posterior stabilized knee systems are designed for use in patients in primary and revision surgery, where the anterior and posterior cruciate ligaments are incompetent and the collateral ligaments remain intact.
5. Constrained knee systems are designed for use in patients in primary and revision surgery, where the posterior cruciate ligament and one or both of the collateral ligaments (i.e. medial collateral and/or lateral collateral ligament) are absent or incompetent.

Prescription Use __X__ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

We are smith&nephew

Submitted by:	Smith & Nephew, Inc. Orthopaedic Division 1450 East Brooks Road Memphis, Tennessee 38116
Date of Summary:	August 5, 2014
Contact Person and Address:	Jenny Waldrip Regulatory Affairs Specialist T 901.399.6022 F 901.721.2735
Name of Device:	Smith & Nephew, Inc. Disposable Fin Punch
Common Name:	Orthopaedic Surgical Instrumentation
Device Classification Name and Reference:	21 CFR 888.3560 Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis 21 CFR 888.3565 Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis
Device Class:	Class II
Panel Code:	Orthopaedics/87
Product Code:	JWH, MBH

Device Description

Per U.S. Food and Drug Administration (FDA) regulation, device-specific instruments are accessory devices and take on the classification of the device(s) with which they are used. Although these instruments are similar in design to 510(k)-exempt orthopaedic manual instruments classified under 21 CFR 888.4540, instruments which assist in the implantation of Class II Smith & Nephew Total Knee Systems and are classified as Class II devices are subject to pre-market notifications and regulations.

The Smith & Nephew Disposable Fin Punch is a line addition to the Smith & Nephew Disposable Knee Instruments that were cleared in K123159. The subject device is intended to cut the bone to prepare the tibia to accept the tibial base implant.

Intended Use

Smith & Nephew Disposable Fin Punch is an accessory device and is intended to be used to assist in the implantation of Smith & Nephew's Genesis II and Legion Knee Systems and their cleared Indications for Use as presented below. Table 5.1 includes the Smith & Nephew Total Knee Systems to be used in conjunction with the subject device.

Table 5.1 Smith & Nephew Inc. Compatible Total Knee Systems

Description	510(k)	Clearance Date
LEGION PRIMARY SYSTEM	K093746	4/14/10
GENESIS II TOTAL KNEE SYSTEM	K951987	8/22/1995
GENESIS II P/S HIGH FLEXION KNEE INSERT	K032295	8/21/03
GENESIS II DEEP FLEXION C/R ARTICULAR INSERT	K041825	3/11/05
TOTAL KNEE SYSTEM INSTRUMENTATION	K121393	8/7/12

Indications for Total Knee Replacement

1. Rheumatoid arthritis.
2. Post-traumatic arthritis, osteoarthritis, or degenerative arthritis in older patients whose age, weight, and activity level are compatible with an adequate long-term result.
3. Failed osteotomies, unicompartmental replacement, or total knee replacement.
4. Posterior stabilized knee systems are designed for use in patients in primary and revision surgery, where the anterior and posterior cruciate ligaments are incompetent and the collateral ligaments remain intact.
5. Constrained knee systems are designed for use in patients in primary and revision surgery, where the posterior cruciate ligament and one or both of the collateral ligaments (i.e. medial collateral and/or lateral collateral ligament) are absent or incompetent.

Technological Characteristics

Mechanical testing has been conducted to address the intraoperative impact loads expected to be experienced by the fin punch. Additionally, biocompatibility testing for the black Polyetherimide (PEI) material was conducted per the recommendations of ISO 10993-1. A review of the results indicates that the Disposable Fin Punch is equivalent to existing, legally marketed predicate instrumentation with regards to mechanical performance and that there are no new issues related to the safety and effectiveness of the subject devices. Clinical data was not needed to support the safety and effectiveness of the subject devices.

Substantial Equivalence Information

The subject devices are identical in function, intended use, and indications for use and very similar in overall design to the GENESIS II Non-Porous Fin-Stem Punch via premarket notification K121393. In addition, the material composition of the subject device is identical to the Disposable Ream-Through Trial cleared via premarket notification K123159. Refer to **Exhibit 4** for Premarket Info for Predicate Devices.

Table 5.2 Substantially Equivalent Predicates to the Disposable Fin Punch

Manufacturer	Description	Submission Number	Clearance Date
Smith and Nephew Inc.	GENESIS II Non-Porous Fin-Stem Punch	K121393	August 7, 2012
Smith and Nephew Inc.	Disposable Ream-Through Trial	K123159	May 3, 2013

Conclusion

As previously noted, this Traditional 510(k) Premarket Notification is being submitted to request clearance for the Smith and Nephew Disposable Fin Punch. Based on the similarities to the predicate devices and a review of the testing performed, the devices are substantially equivalent to above predicate Total Knee Instrumentation.