JUL 2 1 2014

510(k) Summary **Date Prepared: May 23rd, 2014**

SUBMITTER INFORMATION	CONTACT INFORMATION
Smith & Nephew, Inc. 150 Minuteman Road Andover, MA 01810	Vivek Mukhatyar Regulatory Affairs Specialist II Phone: (978)749-1043 Fax: (978)749-1443

DEVICE NAME (UNMODIFIED)	
Trade or proprietary name	BIOSURE HEALICOIL PK Interference Screw
Common or usual name	Soft Tissue Fixation Device
Classification name	21 CFR §888.3040 – Smooth or threaded metallic bone fixation fastener
Device Class	Class II
Product Code	MBI

LEGALLY MARKETED PREDICATE DEVICE

The Smith & Nephew BIOSURE HEALICOIL PK interference screw is substantially equivalent in intended use and Fundamental Scientific Technology to the following legally marketed devices in commercial distribution:

K083635 Smith & Nephew BIOSURE PK
K083226 (Cleared on January 30, 2009)

K042552 Biomet Bio-Core
(Cleared on December 14, 2004)

DEVICE DESCRIPTION

Smith & Nephew BIOSURE HEALICOIL PK interference screw is a non-absorbable, sterile, single-use, interference screw composed of Polyetheretherketone (PEEK). It has a fenestrated open design which allows for bone ingrowth. It is provided in size ranging from 6mm to 10 mm diameter. BIOSURE HEALICOIL interference screw minimizes the volume of material implanted into the body while providing equal fixation strength of a standard interference screw. The central channel of the screw can be packed with autologous bone.

Intended Use

The BIOSURE HEALICOIL PK Interference Screw is indicated for the reattachment of ligament, tendon, soft tissue, or bone-tendon-bone for the following indications:

Knee
ACL repairs
PCL repairs
Extra-capsular repairs
- Medial collateral ligament
- Lateral collateral ligament
- Posterior oblique ligament

Patellar realignment and tendon repairs
- Vastus medialis obliquus advancement

Iliotibial band tenodesis

Shoulder
Acromioclavicular separation repairs
Biceps tenodesis

Foot and Ankle
Medial or lateral instability repairs/reconstructions
Achilles tendon repairs/reconstructions
Metatarsal ligament/tendon repairs/reconstructions
Flexor hullucis longus (FHL) Tendon transfers

Elbow, Wrist, and Hand
Biceps tendon reattachment
Ulnar or radial collateral ligament reconstructions
Lateral epicondylitis repair
Scapholunate ligament reconstruction
Tendon transfers
Carpomedicarpal joint arthroplasty

Technological Characteristics

Smith & Nephew BIOSURE HEALICOIL interference screw is substantially equivalent in intended use and fundamental scientific technology to the legally marketed predicate devices (Smith and Nephew BIOSURE PK - K083226 & K083635 and BIOMET Bio-Core K042552) and raises no new issues of safety and efficacy. Smith & Nephew BIOSURE HEALICOIL interference screw and the predicate Smith & Nephew BIOSURE PK Interference screws (K083226 & K083635) are manufactured from the same PEEK material. Smith & Nephew BIOSURE HEALICOIL interference screw and the predicate Biomet Bio-core (K042552) have a similar open lattice construction to allow for bone ingrowth through the fenestrations to the central channel of the screws or to be packed with autologous bone.

Summary of Performance Data

Mechanical testing data for pull out and insertion testing demonstrates the BIOSURE HEALICOIL PK interference screw is substantially equivalent to the currently marketed predicate devices.

The animal study evaluated bone ingrowth into the BIOSURE HEALICOIL PK interference screw (n=11) and control (n=11) via micro computed tomography (μCT) and histology. μCT demonstrated at twelve weeks that there was bone between the fenestrations and within the central cannulations. Histology analysis

demonstrated that new bone formed within the BIOSURE HEALICOIL PK interference screw and control in the fenestration between the threads into the central channel in all specimens.

Note: Animal data is not necessarily indicative of human clinical outcomes. These results *have not been demonstrated in humans having variety of bone quality based on specific disease states such as osteoporosis.*

SUBSTANTIAL EQUIVALENCE INFORMATION

The substantial equivalence of the BIOSURE HEALICOIL PK interference screw is based on similarities in indications for use, design features, operational principles, material composition, and performance to the predicate devices listed above. Based on the similarities to the predicates, the BIOSURE HEALICOIL PK interference screw is substantially equivalent to its predicates.

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

July 21, 2014

Smith & Nephew, Incorporated
Vivek Mukhatyar, Ph.D.
Regulatory Affairs Specialist II
150 Minuteman Road
Andover, Massachusetts 01810

Re: K140879
Trade/Device Name: BIOSURE HEALICOIL PK Interference Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: May 23, 2014
Received: May 28, 2014

Dear Dr. Mukhatyar:

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 yours,

Ronald P. Jean -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)*

K140879

Device Name
The BIOSURE HEALICOIL PK Interference Screw

Indications for Use *(Describe)*
The BIOSURE HEALICOIL PK Interference Screw is indicated for the reattachment of ligament, tendon, soft tissue, or bone-tendon-bone for the following indications:

Knee
ACL repairs, PCL repairs, Extra-capsular repairs, Medial collateral ligament, Lateral collateral ligament, Posterior oblique ligament, Patellar realignment and tendon repairs, Vastus medialis obliquus advancement, Iliotibial band tenodesis

Shoulder
Acromioclavicular separation repairs, Biceps tenodesis

Foot and Ankle
Medial or lateral instability repairs/reconstructions, Achilles tendon repairs/reconstructions, Metatarsal ligament/tendon repairs/reconstructions, Flexor hullucis longus (FHL), Tendon transfers

Elbow, Wrist, and Hand
Biceps tendon reattachment, Ulnar or radial collateral ligament reconstructions, Lateral epicondylitis repair, Scapholunate ligament reconstruction, Tendon transfers, Carpomedicarpal joint arthroplasty

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."