



Food and Drug Administration
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SIGN Fracture Care International
Mr. Rob Teeter
Regulatory Affairs/Quality Assurance Manager
451 Hills Street, Suite B
Richland, Washington 99354

November 13, 2015

Re: K152757
Trade/Device Name: Sign Hip Construct (SHC)
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB, KTT, HRS
Dated: September 24, 2015
Received: September 24, 2015

Dear Mr. Teeter:

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 Parts 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 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,

Mark N. Melkerson -S

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

Enclosure

Indications for Use

510(k) Number (if known)

K 152757

Device Name

SIGN Hip Construct (SHC)

Indications for Use (Describe)

Indications for the SIGN Hip Construct (SHC) include all peritrochanteric, reverse oblique, subtrochanteric fractures and osteotomies in the proximal femur, with proper soft tissue management.

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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510(k) Summary

510(k) Submitter: SIGN Fracture Care International
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Establishment #: 3034525

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Date Prepared: September 8, 2015

Regulatory Class: Class II

Panel: Orthopedic

Trade Name: SIGN Hip Construct (SHC)

Common Name: Hip Fixation System

Classification Name: 21CFR 888.3020: Intramedullary fixation rod

Device Product Code: HSB, KTT, HRS

Predicate Device: The SIGN Hip Construct (SHC) is similar in design, function, and use to the following fixation devices.

SIGN Hip Construct (SHC) (K083582) - Primary Predicate
SIGN IM Nail (K022632)
Synthes 6.5mm Cannulated Screw (K021932)

Device Description

The SHC is an internal fixation device consisting of multiple components; Standard Hip Nail, Fin Hip Nail (Intramedullary Nails), Bone Plates, Interlocking Screws, Compression Screws, Bone Screws, and a set of Surgical Instruments. Each implant component is made from Stainless Steel, per requirements in ASTM F138 or F139. All implants are single use and provided non-sterile.

Intended Use

Indications for the SIGN Hip Construct (SHC) include all peritrochanteric, reverse oblique, subtrochanteric fractures and osteotomies in the proximal femur, with proper soft tissue management.

The Indications for Use statement is not identical to the predicate device; however, the differences do not alter the intended use of the device nor do they affect the safety and effectiveness of the device relative to the predicate. Both the subject and predicate devices share the intended use of treating proximal femur fractures.

Substantial Equivalence Comparison

The SIGN Hip Construct (SHC) is substantially equivalent to the predicate SHC in design, performance, functions, and intended use. The safety and effectiveness of the SHC is also based on a history of use of this device in SIGN Humanitarian Programs.

The proposed device is very similar to the predicate Hip Construct. The difference in indications is that they have expanded to include reverse oblique fractures, and osteotomies. Osteotomies can be described as a deliberate fracture of the subtrochanteric or peritrochanteric region, which was already included as an indication of the predicate device. Reverse oblique fractures are commonly treated with intramedullary nails and systems such as the predicate SHC. These differences in indication are not critical to the surgical use of the device.

The modified device adds the option of a hip IM nail with standard interlocking and an updated plate design which allows for less prominence from the bone. The SIGN IM Nail was included as a predicate because it uses the same interlocking features and encompasses the size range of the proposed device.

Comparison of Technological Characteristics

The predicate and proposed devices have a similar intended use and basic fundamental scientific technology and share the following similarities.

- Similar indications for use
- Similar design features
- Incorporate the same or similar materials
- Equivalent mechanical performance, based on intended use

Though the proposed modified SHC device has features largely similar to the predicate SHC, the additional lengths and expanded indications prompted non-clinical performance testing.

The predicate SHC device only includes an IM Nail length of 240mm but the SIGN IM Nail design incorporates nails up to 420mm in length, therefore it was included as a predicate and non-clinical testing was performed to ensure safety and effectiveness.

Performance Data (non-clinical)

Fatigue tests simulating walking gait were performed to validate that the device can withstand patient use until fracture consolidation occurs. The primary predicate device was cleared in part based on the results of bench testing. These bench tests were duplicated using the modified

device. Specific tests performed include cyclic fatigue testing. The results did not raise any issues on the safety or effectiveness of the device.

Conclusion

The testing data and design information provided in this submission indicate that the proposed device is safe and effective, and performs as well or better than the predicates. This supports the conclusion that the SIGN Hip Construct (SHC) is substantially equivalent to its predicate device.