



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

February 25, 2016

Re: K153759

Trade/Device Name: SIGN Compression Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: December 16, 2015
Received: December 30, 2015

Dear Mr. Schmitt:

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)

K153759

Device Name

SIGN Compression Screw System

Indications for Use (Describe)

Indications for the SIGN Compression Screw System include intracapsular femoral neck fractures, 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: February 8, 2016

Regulatory Class: Class II

Panel: Orthopedic

Trade Name: SIGN Compression Screw System

Common Name: Orthopedic Bone Screw

Classification Name: 21CFR 888.3040: Smooth or threaded metallic bone fixation fastener

Device Product Code: HWC

Predicate Device: The SIGN Compression Screw System is similar in design, function, and use to the following fixation devices.

1. ASNIS III Cannulated Screw System (K000080) - Primary Predicate
2. SIGN Hip Construct (SHC) (K083582)

Device Description

The SIGN Compression Screw System consists of multiple components; self-tapping compression screws, and a set of surgical instruments. Each implant component is made from Stainless Steel, per requirements in ASTM F138. All implants are single use and provided non-sterile.

Intended Use

Indications for the SIGN Compression Screw System include intracapsular femoral neck fractures, 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 intracapsular femoral neck fractures.

Substantial Equivalence Comparison

The SIGN Compression Screw System is substantially equivalent to the predicate ASNIS III Cannulated Screw System (K000080), in design, performance, functions, and intended use.

The SIGN Hip Construct was included as a predicate because the instruments and implants were cleared under K083582.

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

The proposed SIGN Compression Screw System has an intended use largely similar to the predicate ASNIS III Cannulated Screw System (K000080). The technical features of the proposed device prompted non-clinical performance testing to ensure substantial equivalence.

Performance Data (non-clinical)

Mechanical testing was performed and three performance characteristics were evaluated:

Axial stiffness, load to failure, and cyclic fatigue. The results support substantial equivalence and 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 substantially equivalent, and performs as well or better than the predicates. This supports the conclusion that the SIGN Compression Screw System is substantially equivalent to its predicate device.