DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

July 20, 2017

Re: K163589
Trade/Device Name: Sign IM Nail
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary Fixation Rod
Regulatory Class: Class II
Product Code: HSB, KTT
Dated: June 29, 2017
Received: July 7, 2017

Dear Robert 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 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,

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: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*

K163589

Device Name
SIGN IM Nail System

Indications for Use *(Describe)*

The SIGN IM Nail System is indicated for tibiotalocalcaneal arthrodesis. Specific examples of indications include primary or post traumatic or previously infected arthrosis, failed ankle arthrodesis, failed total ankle replacement, avascular necrosis of the talus, neuromuscular deformity or instability of the ankle, osteoarthritis, nonunions or pseudarthrosis of hindfoot and distal tibia, malunited tibial pilon fracture, charcot foot, severe arthritis, severe defects after tumor resection, pantalar arthrodesis. IM Nail sizes recommended for these indications are 10-12mm diameter and 200-300mm in length.

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.**

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

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# 510(k) Summary

| | |
|---|---|
| **510(k) Submitter:** | SIGN Fracture Care International<br>451 Hills Street, Suite B<br>Richland, WA 99354 |
| **Establishment #:** | 3034525 |
| **Contact Person:** | Robert Schmitt, Regulatory Affairs / Quality Assurance Manager<br>Phone: 509-371-1107<br>Fax: 509-371-1316<br>E-Mail: Bob.Schmitt@signfracturecare.org |
| **Date Prepared:** | July 12, 2016 |
| **Regulatory Class:** | Class II |
| **Panel:** | Orthopedic |
| **Trade Name:** | SIGN IM Nail System |
| **Common Name:** | Orthopedic Intramedullary Rod |
| **Classification Name:** | 21CFR 888.3030: Rod, fixation, intramedullary and accessories |
| **Device Product Code:** | HSB, KTT |

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

- Stryker T2 Ankle Arthrodesis Nail System (K051590) - Primary Predicate
- SIGN IM Nail System (K022632)
- Small Bone Innovations A3 Interlocking Nail System (K112982)
- Carbofix Piccolo Composite Nailing System (K123810)

**Device Description**

The SIGN IM Nail System consists of multiple components; Standard IM Nail, Interlocking 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**

The SIGN IM Nail System is indicated for tibiotalocalcaneal arthrodesis. Specific examples of indications include primary or post traumatic or previously infected arthrosis, failed ankle arthrodesis, failed total ankle replacement, avascular necrosis of the talus, neuromuscular deformity or instability of the ankle, osteoarthritis, nonunions or pseudarthrosis of hindfoot and distal tibia, malunited tibial pilon fracture, charcot foot, severe arthritis, severe defects after

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tumor resection, pantalar arthrodesis. IM Nail sizes recommended for these indications are 10-12mm diameter and 200-300mm in length.

Comparing the Indications for Use statement to that of the primary predicate shows that all indications of the subject device are included by the primary predicate. 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 ankle fusions.

**Substantial Equivalence Comparison**

The SIGN IM Nail System is substantially equivalent to the predicate Stryker T2 Ankle Arthrodesis Nail System (K051590), in design, performance, functions, and intended use.

The SIGN IM Nail System was included as a predicate because the instruments and implants were previously cleared under K022632.

**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 IM Nail System has an intended use largely similar to the predicate Stryker T2 Ankle Arthrodesis Nail System (K051590). The technical features of the proposed device prompted non-clinical performance testing to ensure safety and effectiveness. Differences between the subject device and primary predicate are summarized as following; the subject device is not cannulated, uses different implant materials, has differing IM Nail lengths, differing IM Nail bend angles, differing screw hole diameters, differing screw hole distances, and differing slot lengths. Accompanying screw differences include major and minor diameters, screw length, and full/partially threaded screw options.

The technological characteristics evaluated and found to be similar to one or more of the predicate devices named above include IM nail diameter, IM nail core, IM nail lengths, IM nail bend angles, static/dynamic interlocking options, screw hole diameter, number of proximal and distal screws, distance between holes, screw length, screw thread major diameter, screw shank diameter, screw pitch, screw length, full or partially threaded screws, and implant material.

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**Performance Data (non-clinical)**

The non-clinical tests performed by the company include an analysis of strength of the SIGN IM Nail System. The results of the performed tests support substantial equivalence to legally marketed predicate devices and did not raise any issues on the safety or effectiveness of the device.

**Conclusion**

Non-clinical testing was conducted, as well as an analysis of technological characteristics comparing the subject device to the predicate devices. The results support the conclusion that the SIGN IM Nail System is substantially equivalent to its predicate device.