March 10, 2022

SIGNUS Medizintechnik GmbH
℅ Carolyn Guthrie
Director of Regulatory & Quality
Kapstone Medical, LLC
520 Elliot St.
Charlotte, North Carolina 28202

Re: K212755
Trade/Device Name: SACRONAIL Transsacral Stabilization System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC, JDS
Dated: February 7, 2022
Received: February 9, 2022

Dear Carolyn Guthrie:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K212755

Device Name
SIGNUS SACRONAIL® Transsacral Stabilization System

Indications for Use *(Describe)*
The SIGNUS SACRONAIL® Transsacral Stabilization System is intended for fixation of fractures of the posterior pelvis, in areas of superior posterior iliac spine and posterior inferior iliac spine, for sacral fractures and fracture-dislocations of the sacro-iliac joint.

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

In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular 21 CFR 807.92, the following summary of information is provided.

## 1. Date of Preparation:

October 07, 2021

## 2. Applicant

SIGNUS Medizintechnik GmbH
Industriestrasse 2
63755 Alzenau, Germany

## 3. Official Correspondent

Kapstone Medical LLC
520 Elliot St.
Charlotte, NC 28202

## 4. Contact Person:

Carolyn Guthrie
Email: cguthrie@kapstonemedical.com

## 5. Device Name

Trade Name: SIGNUS SACRONAIL® Transsacral Stabilization System
Common Name: Pelvic Joint Fixation
Regulation Description: Smooth or Threaded metallic bone fixation fastener
Regulation Number: 21 CFR 888.3040, 21 CFR 888.3030
Product Code: HWC
Secondary Product Code: JDS
Classification: Class II
Panel: Orthopedic

## 6. Predicate Devices

Primary Predicate

| Trade Name | Clearance | Claim of Equivalence for: | 510(k) holder |
|---|---|---|---|
| Sacral Bar | K001720 | Predicate Device | Depuy/Synthes |

Additional Predicates

| Trade Name | Clearance | Claim of Equivalence for: | 510(k) holder |
|---|---|---|---|
| Dynanail Mini Hybrid | K203381 | Additional Predicate Device | MedShape Inc. |
| 7.3 mm Cannulated Screws | K161616 | Additional Predicate Device | DePuy/Synthes |
| M.U.S.T. Sacral Iliac and Pelvic Trauma System | K171595 | Additional Predicate Device | Medacta International SA |

Table 5.1: Predicate devices

## 7. Indications for Use

The SIGNUS SACRONAIL® Transsacral Stabilization System is intended for fixation of fractures of the posterior pelvis, in areas of superior posterior iliac spine and posterior inferior iliac spine, for sacral fractures and fracture-dislocations of the sacro-iliac joint.

## 8. Device Description

The SACRONAIL system provides a sustained, stable restoration of dorsal pelvic fractures and sacral fractures through its intraosseous location and its direct, bi-iliac symmetric anchorage.

The implant consists of a nail of various lengths from135mm to 194mm with a constant diameter of 8mm and 2 locking screws in different lengths. This variation ensures adaptation to the respective anatomy of the patient. The intersections of the screw axes to the implant axis have a distance of 15mm to the respective end face of the nail. This ensures a solid support on the lateral cortex of the Ilia. The angle of the screw axes to

the implant axis corresponds to the anatomical conditions and is 70°. The locking screw ensures a stable connection of the components. The tips of the locking screws are rounded to facilitate insertion into the nail while the dorsal ends of locking screws are a hexagon. The caps serve to close the instrument connection of the nail. The implants are made from the Titanium alloy (Ti6Al4V) according to ASTM F 136 / ISO 5832-3, with a Type II anodization according to AMS 2488.

There are Instruments which are specific to the implantation of the SACRONAIL device. These include, but are not limited to, the Guide Frame, the Guide Bracket, the Fixation Bracket, various Instrument Guides, various dilators and drills, screwdrivers as well as the specific tools for revision of the device.

## 8.1 Product Name

SIGNUS SACRONAIL® Transsacral Stabilization System

## 8.2 Intended Performance

The SACRONAIL system is intended to a sustained, stable restoration of dorsal pelvic fractures and sacral fractures through its intraosseous location and its direct, bi-iliac symmetric anchorage.

## 9. Comparison of Technological Characteristics with the Predicate Devices

The subject device SACRONAIL® Transsacral Stabilization System was shown to be substantially equivalent and have the same technological characteristics to a previously FDA cleared predicate device through comparison in areas including, intended use, material composition, and function through the means of mechanical and biomechanical cadaveric comparison. Any technical differences, which were identified and discussed in this submission, do not result in new questions of safety or effectiveness.

## 10. Performance Data

There are no clinical data generated and held by the manufacturer, i.e., no pre-marketing or post-market clinical studies or animal studies have been performed. The following information is provided in support of substantial equivalence.

### 10.1 Biocompatibility

The SACRONAIL® Transsacral Stabilization System is classified as an implant device with tissue/bone contact and permanent contact. Therefore, according to ISO 10993-1 the biological evaluation was assessed for potential effects.

The SACRONAIL® Transsacral Stabilization System is manufactured from Titanium Alloy per ASTM F136. The evaluation was based on product-specific tests and on published literature data. This approach is considered feasible as Titanium Alloy is a well-established material in the medical field.

The available data from the raw material manufacturer, the testing performed on the finished device, and published literature form the basis of the biological evaluation for the SACRONAIL® Transsacral Stabilization System.

The presented results in this submission show that pedicle screw systems made from Titanium Alloy per ASTM F136 have a high demonstrable biological safety. No concerns arose that would preclude clinical use of SACRONAIL® Transsacral Stabilization System. The requirements of the ISO 10993 standard series are fulfilled.

### 10.2 Mechanical Testing

Testing according to

- ASTM F1264-16 Standard Specification and Test Method for Intramedullary Fixation Devices
- ASTM F1717-15: Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model
- ASTM F543 Standard Specification and Test Methods for Metallic Medical Bone Screws

was performed to demonstrate equivalence to predicates.

The detailed mechanical testing shows that in summary, the SACRONAIL® Transsacral Stabilization System provides equivalent mechanical properties compared to the predicate for this intended use.

### 10.3 MR Safety Testing

The SACRONAIL® Transsacral Stabilization System has not been evaluated for safety, heating, migration, or compatibility in the MR environment. The SACRONAIL® Transsacral Stabilization System has not been tested for heating, migration or image artefact in the MR environment. The safety of the SACRONAIL® Transsacral Stabilization System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

## 11 Conclusion

The SIGNUS SACRONAIL® Transsacral Stabilization System and the predicate device have the similar intended use in sacral and pelvic fractures and are available by prescription only. The SACRONAIL System implants are provided sterile (Instruments are provided non-Sterile). Any technical differences, which were identified, do not result in new questions of safety or effectiveness.

Through assessment of technological characteristics, intended use and the biomechanical performance data provided, it can be concluded that SIGNUS SACRONAIL® Transsacral Stabilization System is substantially equivalent to the predicate device for this intended use.