Stuckenbrock Medizintechnik GmbH
Fabian Stuckenbrock
President
Lessingstrasse 50
78532 Tuttlingen
Germany

January 12, 2018

Re: K171628
Trade/Device Name: HBS2 Headless Bone Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: December 26, 2017
Received: December 18, 2017

Dear Fabian Stuckenbrock:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Katherine D. Kavlock -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)*
K171628

Device Name
HBS2 Headless Bone Screw

Indications for Use *(Describe)*
HBS2 Headless Bone Screw is used for the treatment of intraarticular and extraarticular fractures and pseudoarthroses of smaller bones and bone fragments as well as for arthrodeses on small joints, especially in the scope of:

HBS2 MIDI: Scaphoid fractures, Scaphoid pseudoarthroses, Proximal pole fractures of the scaphoid, DIP arthrodeses, Metacarpal fractures, Metatarsal fractures, Fractures of the processus styloideus ulnae, Proximal radial head fractures

HBS2 MINI: Scaphoid fractures, Scaphoid pseudoarthroses, Proximal pole fractures of the scaphoid, DIP arthrodeses, Metacarpal fractures, Fractures of the processus styloideus ulnae, Proximal radial head fractures, Fractures of the processus styloideus radii

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)
HBS2 Headless Bone Screw

Stuckenbrock Medizintechnik
ein Unternehmen der KLS martin Group

K171628

510(k) Summary

Issue Date: **18-12-2017**

510(k) Owner´s Name:

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Lessingstrasse 50
78532 Tuttlingen
Germany
Tel: + 49 (0)7461/165880
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Internet: www.stuckenbrock.de

Contact Person:

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Tel.: +49 7461 165880
E-Mail: f.Stuckenbrock@stuckenbrock.de

1. General Info

1.1. Device Name

Trade Name: HBS2 Headless Bone Screw

Common Name: Bone fixation screw

Classification Name: Screw, fixation, bone

1.2. Classification Product Code

Stuckenbrock HBS2 Headless Bone Screw can be classified according to following device name and product code:

Device	Regulation Description	Regulation Medical Specialty	Review Panel	Product Code	Regulation Number	Device Classification
Screw, fixation, bone	Smooth or threaded metallic bone fixation fastener	Orthopedic	Orthopedic	HWC	888.3040	2

2. Indication for Use

HBS2 Headless Bone Screw is used for the treatment of intraarticular and extraarticular fractures and pseudoarthroses of smaller bones and bone fragments as well as for arthrodeses on small joints, especially in the scope of:

- *HBS2 MIDI:*
  - Scaphoid fractures
  - Scaphoid pseudoarthroses
  - Proximal pole fractures of the scaphoid
  - DIP arthrodeses
  - Metacarpal fractures
  - Metatarsal fractures
  - Fractures of the processus styloideus ulnae
  - Proximal radial head fractures
- *HBS2 MINI:*
  - Scaphoid fractures
  - Scaphoid pseudoarthroses
  - Proximal pole fractures of the scaphoid
  - DIP arthrodeses
  - Metacarpal fractures
  - Fractures of the processus styloideus ulnae
  - Proximal radial head fractures
  - Fractures of the processus styloideus radii

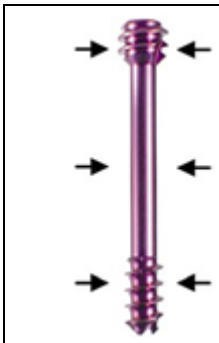
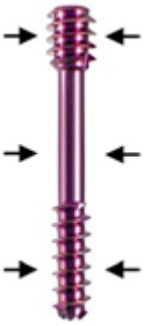
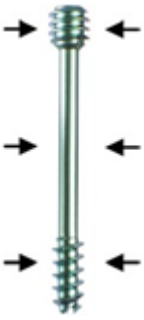
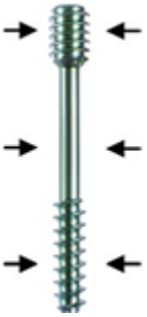
3. Device Description

The HBS2 Headless Bone Screws are used in the field of hand surgery, accident surgery and reconstructive surgery, and in orthopedics for the treatment of intraarticular and extra articular fractures and pseudo arthroses of small bones and bone fragments, and for arthrodesis on small joints.

The system consists of various screws and instruments for different treatment options.

HBS2 screws are cannulated, self-drilling, self-cutting, have a reversing thread and are available in two diameters with different thread lengths.

HBS2 MIDI screws (magenta) are available with a diameter of 2.0 mm (shaft) and in different lengths. HBS2 MINI screws (green) are available with a diameter of 1.7 mm (shaft) and in different lengths too.

<table>
<tr><td rowspan="3">  </td><td>Ø 3.9 mm
Thread pitch 1.0 mm</td><td rowspan="3">  </td></tr>
<tr><td>Ø 2.0 mm</td></tr>
<tr><td>Ø 3.0 mm
Thread pitch 1.25 mm</td></tr>
<tr><td rowspan="3">  </td><td>Ø 3.2 mm
Thread pitch 0.75 mm</td><td rowspan="3">  </td></tr>
<tr><td>Ø 1.7 mm</td></tr>
<tr><td>Ø 2.5 mm
Thread pitch 1.0 mm</td></tr>
</table>

These devices are delivered in non-sterile condition and must be reprocessed before use.

All implants are made out of Ti6Al4V 3.7165.

4. Predicate Devices

4.1. Primary Predicate Device

- *HBS HEADLESS BONE SCREW, SCHOENING & ASSOC., INC., K030302*

4.2. Secondary Predicate or Reference Devices

- *SYNTHES 2.4 MM CANNULATED COMPRESSION SCREW, SYNTHES (USA), K021556*
- *SYNTHES 3.0MM HEADLESS COMPRESSION SCREWS, SYNTHES (USA), K050636*

4.2.1. Substantial Equivalence Claimed to predicate Devices

The Stuckenbrock HBS2 headless bone screws are substantially equivalent to the predicate devices in terms of intended use, design, materials used, mechanical safety and performance.

5. Clinical and Non-Clinical Test Summary

5.1. Clinical Tests

No clinical studies were performed.

5.2. Non-Clinical Test Summary

The follow tests have been conducted:

Topic	Standard	Test
Biological Safety	EN ISO 10993-5	Cytotoxicity
	EN ISO 10993-12	Chemical Analysis – Characterization of Organic Extractable
	EN ISO 10993-18	
	EN ISO 11737-1	Bioburden
	USP 85	LAL Endotoxin
	USP 788	Particle
Mechanical Safety	ASTM F543-07 --- ASTM F116-00 --- ASTM F1839-08	Torsional properties
		Driving torque
		Axial pullout strength
	ASTM F1264-03	Static 3-point bending Dynamic 3-point bending

Sensible manufacturing processes have been validated (e.g. Final Cleaning). Furthermore, reprocessing process has been validated in terms of:

- ❒ *Pre-Treatment*
- ❒ *Manual Cleaning*
- ❒ *Automated Cleaning/Disinfection (thermal disinfection)*
- ❒ *Drying*
- ❒ *Sterilization*

5.2.1. Conclusions Non-Clinical Tests

Stuckenbrock considers the HBS2 headless bone screws to be equivalent to the predicate devices listed above. This conclusion is based upon the device's similarities in principles of operation, technology, materials, and indications for use.