



January 25, 2019

Stryker GmbH
Jackie Perri
Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K182968

Trade/Device Name: Hoffmann LRF System

Regulation Number: 21 CFR 888.3030

Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances and Accessories

Regulatory Class: Class II

Product Code: KTT

Dated: January 10, 2019

Received: January 11, 2019

Dear Ms. Perri:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

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,

**Peter G.
Allen -S** Digitally signed by
Peter G. Allen -S
Date: 2019.01.25
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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

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

Indications for Use

510(k) Number (if known)

K182968

Device Name

Hoffmann LRF System

Indications for Use (Describe)

The Stryker Hoffmann LRF System is indicated in pediatric patients and adults for the treatment and fixation of:

- Open and Closed Fractures
- Post-traumatic joint contracture which has resulted in loss of range of motion
- Fractures and disease which generally may result in joint contractures or loss of range of motion and fractures requiring distraction
- Pseudoarthrosis or non-union of long bones
- Limb lengthening by epiphyseal, diaphyseal, or metaphyseal distraction
- Correction of bony or soft tissue deformity
- Correction of segmental bony or soft tissue defects
- Joint arthrodesis
- Management of comminuted intra-articular fractures of the distal radius
- Bone transport

The Hoffmann LRF System is indicated in adults for:

- Osteotomy
- Revision procedure where other treatments or devices have been unsuccessful
- Bone reconstruction procedures
- Fusions and replantations of the foot
- Charcot foot reconstruction
- Lisfranc dislocations

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

Submitter: Stryker GmbH
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Switzerland

Contact Person: Jackie Perri
Regulatory Affairs Specialist
Phone: (732) 770-5616
Email: jackie.perri@stryker.com

Date Prepared: October 2, 2018

Name of Device: Hoffmann LRF System

Common or Usual Name: External Fixation Device

Classification Name: Single/multiple component metallic bone fixation appliances and accessories (21 CFR § 888.3030)

Regulatory Class: Class II

Product Code: KTT

Primary Predicate: Hoffmann LRF System, K163656

System Description:

The Hoffmann LRF System is a modular, ring-based, external fixation system designed to address certain orthopedic conditions of the limbs. Through a series of pins and wires, the bone is connected to this system with the rings statically placed, or gradually manipulated, depending on the type of correction needed. The modular design allows the system to be customized according to the needs of the patient and utilizes stainless steel, aluminum, PEEK, and carbon fiber.

Components of the following systems may be used with this system: Monticelli-Spinelli External Fixation System, Apex Pins, Trauma Pelvic Set, Hoffmann II External Fixation System, Hoffmann 3 External Fixation System, Hoffmann II External Fixation System 90° Post, Hoffmann II Miami Post, Hoffmann II Carbon Connecting Rods, Hoffmann II MRI External Fixation System, and Hoffmann II Compact MRI External Fixation System. Use of these components does not confer MRI compatibility to the Hoffmann LRF System.

Intended Use:

The Hoffmann LRF System is intended for fixation of fractures, joint contractures, fusions, limb lengthening, deformity correction, and bone and soft tissue reconstruction in pediatric patients and adults.

Indications for Use:

The Stryker Hoffmann LRF System is indicated in pediatric patients and adults for the treatment and fixation of:

- Open and Closed Fractures
- Post-traumatic joint contracture which has resulted in loss of range of motion
- Fractures and disease which generally may result in joint contractures or loss of range of motion and fractures requiring distraction
- Pseudoarthrosis or non-union of long bones
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Comparison of Technological Characteristics:

Comparison of subject and predicate systems demonstrated a shared use of material, fundamental design, and general operating principles in support of the claim of substantial equivalence.

Performance Data:

Non-Clinical Testing

Comparative mechanical testing to the predicate system demonstrated substantial equivalence.

The following tests were performed:

- Corrosion Test
- Self-holding Function Test Over Time
- Pullout Test

Clinical Testing

Clinical testing was not required to be provided for this submission.

Conclusion:

With the exception of the modifications described in the Executive Summary, the Hoffmann LRF System described in this submission is identical to the previously cleared and primary predicate, K163656. Mechanical testing demonstrated that subject system performs as intended and at least as well as the predicate. Based on these attributes, the subject system is deemed substantially equivalent.