DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 11, 2016

Stryker Gmbh
Mr. Paul Nelson
Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K153377
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: March 11, 2016
Received: March 14, 2016

Dear Paul Nelson:

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

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)*
K153377

Device Name
Hoffmann LRF System

Indications for Use *(Describe)*
The 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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Submitter: Stryker GmbH
Bohnackerweg 1
CH-2545 Selzach
Switzerland

Contact Person: Paul Nelson
Regulatory Affairs Specialist
Phone: (201) 831-5691
Fax: (201) 831-6500

Date Prepared: November 20, 2015

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, K140961
Additional Predicate: External Fixation System (Ilizarov), K031181

Device Description:

Hoffmann LRF (Limb Reconstruction Frame) 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. This system utilizes stainless steel, aluminum, PEEK, and carbon fiber.

This submission extends K140961 by introducing a new strut and associated components. This strut can be used in all Hoffmann LRF applications that do not require the use of a foot ring, but are specifically designed for bone lengthening and bone transport. Total components added to the Hoffmann LRF System with this submission: Transport Strut, Bone Transport Strut End Cap, Safety Clip, and Lengthening Ruler, all of which are single-use, and a Tray, which is multi-use. All are provided nonsterile.

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
- 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

Comparison of Technological characteristics with the Predicate Devices:

The subject Hoffmann LRF, predicate Hoffmann LRF, and Ilizarov systems share common materials and utilize the same general principles of operation. All bones involved with the correction are bound to, and manipulated by, an external, ring-based frame system through a series of pins and wires. Corrections are communicated to the bone through this system of connections via a prescribed protocol of stabilization, or gradual movements.

The subject and predicate devices share the following technological characteristics:

- External, ring-based frame approach
- Pins and wires connecting bone to frame
- Similar materials

The subject and predicate devices have the following dissimilar technological characteristics:

- Method by which rings can be moved vertically
- Ability to angulate rings

Performance Data:

Non-Clinical Testing

Comparative mechanical testing to the Ilizarov predicate system demonstrated substantial equivalence.

The following component tests were performed:

- Static four-point bending
- Dynamic four-point bending
- Static cantilever bending
- Dynamic cantilever bending

The following frame construct tests were performed:

- Static compression
- Dynamic compression

Clinical Testing

Clinical testing was not performed, or required, for this submission.

Conclusion:

With the exception of the strut and associated components, the Hoffmann LRF system in this submission is exactly the same as the previously cleared, and primary predicate, system, K140961. Compared to the Ilizarov additional predicate, K031181, the subject system shares the same intended use, patient population, and principles of operation, as well as similar materials and technological characteristics. Mechanical testing demonstrated that the subject system performs as intended and at least as well as the predicate. Based on these attributes, the subject device is deemed substantially equivalent.