July 29, 2022

Stryker Spine
Garry T. Hayeck, Ph.D.
Senior Regulatory Affairs Specialist
2 Pearl Court
Allendale, New Jersey 07401

Re: K142114
Trade/Device Name: Xia® Growth Rod Conversion Set
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: PGM

Dear Dr. Hayeck:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated October 27, 2014. Specifically, FDA is updating this SE Letter because FDA has better categorized your device technology under regulation number, 21 CFR 888.3070.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Ronald Jean, OHT6: Office of Orthopedic Devices, (301)796-5650, Ronald.Jean@fda.hhs.gov.

Sincerely,

Ronald P. Jean -S

Ronald P. Jean, Ph.D.
Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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

October 27, 2014

Stryker Spine
Garry T. Hayeck, Ph.D.
Senior Regulatory Affairs Specialist
2 Pearl Court
Allendale, New Jersey 07401

Re: K142114
Trade/Device Name: Xia® Growth Rod Conversion Set
Regulatory Class: Unclassified
Product Code: PGM
Dated: July 31, 2014
Received: August 4, 2014

Dear Dr. Hayeck:

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 yours,

Ronald P. Jean -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)*
K142114

Device Name
Xia® Growth Rod Conversion Set

Indications for Use *(Describe)*
The Xia® Growth Rod Conversion Set is indicated in patients with potential for additional spinal growth under 10 years of age who require surgical treatment to obtain and maintain correction of severe, progressive, life-threatening, early-onset spinal deformities associated with thoracic insufficiency, including early-onset scoliosis. The Xia® Growth Rod Conversion Set may be used with any cleared Xia® 4.5 Spinal System rod construct. The Xia® Growth Rod Conversion Set is not intended for use in conjunction with staples.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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: Stryker Spine Xia® Growth Rod Conversion Set	
Submitter	Stryker Spine 2 Pearl Court Allendale, NJ 07401
Contact Person	Garry T. Hayeck, Ph.D. Senior Regulatory Affairs Specialist Phone: 201-760-8043 Fax: 201-760-8406 E-mail: garry.hayeck@stryker.com
Date Prepared	September 29, 2014
Trade Name	Xia® Growth Rod Conversion Set
Common Name	Growing Rod System
Proposed Class	Unclassified
Product Code	PGM
Predicate and Reference Devices	The Xia® Growth Rod Conversion Set was shown to be substantially equivalent to the primary predicate device listed below: Medtronic Sofamor Danek, CD HORIZON® Growth Rod Conversion Set, K133904 The following reference device was also cited in support of this submission: Stryker Spine, Xia® 4.5 Spinal System, K121342
Device Description	The Xia® Growth Rod Conversion Set consists of connectors designed to convert a traditional fusion construct into a non-fusion growth enabling construct that can be surgically lengthened on a periodic basis as the patient grows. The Xia® Growth Rod Conversion Set components are manufactured from titanium alloy and are designed to interact with constructs consisting of hooks, screws, connectors, and 4.5mm diameter rods. The Xia® Growth Rod Conversion Set is intended for use only with Xia® 4.5 Spinal System fusion constructs cleared for pediatric use.
Indications for Use	The Xia® Growth Rod Conversion Set is indicated in patients with potential for additional spinal growth under 10 years of age who require surgical treatment to obtain and maintain correction of severe, progressive, life-threatening, early-onset spinal deformities associated with thoracic insufficiency, including early-onset scoliosis. The Xia® Growth Rod Conversion Set may be used with any cleared Xia® 4.5 Spinal System rod construct. The Xia® Growth Rod Conversion Set is not intended for use in conjunction with staples.
Summary of Technological Characteristics	Characteristics of the Xia® Growth Rod Conversion Set are substantially equivalent to those of the above mentioned CD HORIZON® Growth Rod Conversion Set based on material, geometry, intended use, and fundamental scientific technology.

Summary of the Performance Data	Engineering analysis demonstrated that introduction of the Growth Rod Conversion Set does not adversely affect performance of the Xia® 4.5 Spinal System and does not represent a new, worst case scenario. No additional performance data was provided.
Conclusion	This system is as safe and effective as the previously cleared CD HORIZON® Growth Rod Conversion Set listed above due to their shared technological and material characteristics, and principles of operation.