May 15, 2018

Orthofix Srl
Gianluca Ricadona
Sr. Quality & Regulatory Affairs Manager
Via delle Nazioni, 9
97012 Bussolengo (VR)
Italy

Re: K180624
Trade/Device Name: Guided Growth Plate System Plus
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: OBT
Dated: April 24, 2018
Received: April 25, 2018

Dear Gianluca Ricadona:

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,

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)*
K180624

Device Name
Guided Growth Plate System Plus

Indications for Use *(Describe)*
The Guided Growth Plate System Plus is intended for redirecting the growth of long bones.
It is indicated for gradually correcting angular growth deformities in growing children. Specific conditions/diseases for which the device will be indicated include: valgus, varus or flexion, extension deformities of the knee (femur and/or tibia); valgus, varus, or plantar flexion deformities of the ankle; valgus or varus deformities of the elbow (humerus), and radial or ulnar deviation, flexion or extension deformities of the wrist (radius).

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

(as required by 21 CFR 807.92)

Submitter	Orthofix Srl	
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Telephone	+ 39 045 6719.000	
Fax	+ 39 045 6719.380	
Contact Person	Gianluca Ricadona Sr. Quality & Regulatory Affairs Manager	
Address	Via delle Nazioni, 9 37012 Bussolengo (VR) - Italy	
Telephone	+ 39 045 6719.000	
Fax	+ 39 045 6719.380	
email	GianlucaRicadona@orthofix.it	
Preparation date	5/3/2018	
Trade Name	Guided Growth Plate System Plus	
Common Name	Bone plate	
Panel Code	87 / Orthopaedic	
Classification Name	plate, bone, growth control, pediatric, epiphysiodesis	
Class	Class II	
Regulation Number	21 CFR 888.3030	
Product Code	OBT	
Name of Predicate Device	**510(k) #**	**Manufacturer**
Guided Growth Plate System Plus	K172183	Orthofix Srl
Fixation staples - *Blount Staple Epiphyseal* (Reference device)	K834513	STRYKER CORP.
Pediloc Fragment System	K140431	OrthoPediatrics Corp
Description	The Subject new 3.5mm thread diameter screw is a gamma extension of the existing screws (thread Ø4.5mm), components of the predicate Guided Growth Plate System Plus (K172183). The Subject device is a 3.5mm thread diameter screw, available in three lengths and manufactured by the same material (Ti6Al4V), as the 4.5mm diameter gamma screws, included in the predicate Guided Growth Plate System Plus (K172183).	
Indications for use	The Guided Growth Plate System Plus is intended for redirecting the growth of long bones. It is indicated for gradually correcting angular growth deformities in growing children. Specific conditions/diseases for which the device will be indicated include: valgus, varus or flexion, extension deformities of the knee (femur and/or tibia); valgus, varus, or plantar flexion deformities of the ankle; valgus or varus deformities of the elbow (humerus), and radial or ulnar deviation, flexion or extension deformities of the wrist (radius).	
Technological Characteristics and Substantial Equivalence	Documentation was provided to demonstrate that the Subject device is substantially equivalent to the predicate Guided Growth Plate System Plus	

	(K172183) component(s), in the following fundamental aspects: indications for use, intended patient population, system composition, implant material, method of fixation, packaging configuration, sterilization method, biocompatibility and MRI compatibility. Respect to the predicate (K172183), the Subject device is a design dimensional specification change for the introduction of the new thread diameter 3.5mm screw.
Performance data	The design dimensional specification change of the Subject device has been managed by design control activity and Risk Management process. The potential identified risks have been measured and mitigated through mechanical testing and clinical literature analysis, in order to demonstrate that the Subject Device does not introduce additional risks respect to the predicate (K172183). The testing activity results demonstrated to meet the established acceptance criteria. The following standards have been followed to perform mechanical test on the Subject device: • ASTM F564 – 17 “Standard Specification and Test Methods for Metallic Bone Staples”. • ASTM F1264 -16 “Standard Specifications and Test Methods for Intramedullary Fixation Devices”. • ASTM F543 – 17 “Standard Specification and Test Methods for Metallic Medical Bone Screws”. The functional mechanical testing results are supported by the clinical literature analysis, conducted to demonstrate the clinical equivalence between the two alternative clinical procedure by: - using the plate and screw system “Guided Growth plate” K031493 – master Orthofix System for pediatric growth control and epiphysiodesis treatment), - using the staples, chosen as reference devices for the performance data.
Biocompatibility data	The Subject device is equivalent in its final finished form to the predicate device, Guided Growth Plate System Plus (K172183), concerning the: manufacturing, sterilization, processing, geometry, material, intended population, anatomical location and duration of exposure. Therefore, no additional biocompatibility assessment was required for the Subject device.
Conclusion	The analysis on the performance data within this Premarket Notification supports the conclusion that the new Subject gamma size 3.5mm thread diameter screw is safe and effective as the predicate (K172183).