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

January 9, 2018

Re: K172183
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: November 27, 2017
Received: November 29, 2017

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)*

K172183

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.

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

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510(k) Premarket Notification
Guided Growth Plate System Plus

510(k) Summary
(as required by 21 CFR 807.92)

Submitter	Orthofix Srl
	Via delle Nazioni, 9 37012 Bussolengo (VR) - Italy
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

Date Prepared	07/14/2017

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 System Quad-Plate	K093442	Orthofix Srl

Description	The Guided Growth Plate System Plus is designed for the gradual correction of pediatric congenital as well as acquired deformities in both the upper and lower extremities, provided that the physis (growth plates) are not fused. It consists of different sizes of eight-Plate and quad-Plate plus with different cannulated and solid screw options. The plates feature a contoured waist and low profile for pediatric usage. There is a center hole in the plates for a temporary guide pin to be implanted, in order to aid application and removal of the plate. The plates are attached to the external surface of the bone by screws, which are not locked to the plate but rather they are allowed to swivel and diverge in their position as bone growth occurs. The implant acts like a flexible hinge, permitting growth at the growth plate to gradually straighten the limb.

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 System Quad-Plate (K093442) in the following fundamental aspects: intended use, indications for use, site of application, patient population, condition of use, technological characteristics, materials, mechanical performances and implantable components. Respect to the predicate, the Subject device provides design improvements and additional dimensions for implantable components, new sterile components and new related packaging configuration.

Performance Data	The potential hazards have been evaluated and controlled through a Risk Management Plan. All testing met or exceeded the requirements, as established by the test protocols and applicable standard. A review of the mechanical data indicates that the components of the Subject device continues to be capable of withstanding expected loads without failure. The Subject device was therefore found to be substantially equivalent to the Predicate device and has the mechanical properties to perform its indications safely. Clinical data was not needed to support the safety and effectiveness of the Subject Device. The following standard has been followed to perform mechanical test on the System configuration: • ASTM F564 – 10 “Standard Specification and Test Methods for Metallic Bone Staples”.
Biocompatibility data	In order to establish the Subject device non-pyrogenicity, some tests were performed on an equivalent System devices, according to the following international standard: • USP 38: 2014 < 85 > “Bacterial endotoxin test (LAL)”. • USP 38: 2014 < 161 > “Medical devices – bacterial endotoxin and pyrogen tests”. • ANSI / AAMI ST72: 2011 “Bacterial endotoxins – Test methodologies, routine monitoring and alternative batch testing”. • FDA 2012 Q&A “Guidance for Industry Pyrogen and Endotoxins Testing: Question and Answers”. Here below the tests reports and rationale references list: • 8 Plate Plus_QE_RA01_r1, test rationale • Orthofix Biological Evaluation report, dated 2015/05/11 • 16VA00534 validation report, dated 2015/05/11

Conclusion	Based upon similarities in: intended use, indications for use, site of application, patient population, condition of use, technological characteristics, materials, mechanical performances, technology, materials and implantable components, Guided Growth Plate System Plus has been shown to be substantially equivalent to the legally marketed predicate device and to be safe and effective for its intended use.