May 29, 2019

New Standard Device DBA Metalogix
% Nathan Wright
Engineer & Regulatory Specialist
Empirical Consulting LLC
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K181630
Trade/Device Name: Revolution External Plating 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: April 25, 2019
Received: April 29, 2019

Dear Nathan Wright:

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,

for CAPT Raquel Peat, PhD, MPH, USPHS
Director
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181630

Device Name
Revolution External Plating System

Indications for Use *(Describe)*
The Revolution External Plating System is indicated for treatment of a variety of broken or deformed bones:

- Stabilizes open and/or unstable fracture of complex proximal and/or distal tibial fractures
- Fusions of the joints and bone (hand, foot, long-bone)
- Correction of bone or soft tissue deformities
- Correction of segmental or non-segmental bone, soft tissue defects or bone loss
- Neutralization of fractures stabilized with limited internal fixation
- Adult and Pediatric subgroups except newborns

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's Name:	New Standard Device DBA Metalogix
Submitter's Address:	4766 Research Drive San Antonio Texas 78240 USA
Submitter's Telephone:	(210)492-1511
Contact Person:	Nathan Wright, MS Empirical Consulting LLC 719-351-0248
Date Summary was Prepared:	18 Jun 2018
Trade or Proprietary Name:	Revolution External Plating System
Common or Usual Name:	External fixator
Classification:	Class II per 21 CFR §888.3030 Device Classification
Product Code:	KTT
Classification Panel:	Orthopedic

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

Revolution is an external open ring fixation system to provide stability for long bone fractures, limb lengthening, and correction of bone deformities all at a distance from the operative focus.

When used with other components this device stabilizes open and/or unstable fractures of long bones including intracapsular, intertrochanteric, supracondylar, or condylar. It is also used for joint fusions and limb lengthening of deformity corrections which involve cutting the bone.

INDICATIONS FOR USE

The Revolution External Plating System is indicated for treatment of a variety of broken or deformed bones:

•Stabilizes open and/or unstable fracture of complex proximal and/or distal tibial fractures
•Fusions of the joints and bone (hand, foot, long-bone)
•Correction of bone or soft tissue deformities
•Correction of segmental or non-segmental bone, soft tissue defects or bone loss
•Neutralization of fractures stabilized with limited internal fixation
•Adult and Pediatric subgroups except newborns

The indications for use for the Revolution External Plating System are similar to that of the predicate devices.

TECHNOLOGICAL CHARACTERISTICS

Revolution is an external open ring fixation system to provide stability for long bone fractures, limb lengthening, and correction of bone deformities all at a distance from the operative focus.

A plating system consists of a stacked welded plate module and a footplate. These two plates are connected by four super-struts attached by the surgeon to give the best support for the patient. Once assembled, the module is attached to the patient's limb with half-pins or wires. The half-pins are threaded pins with a buttress thread form. Half pins come in three sizes, 4mm, 5mm, and 6mm. Half pins comes in 215mm overall length, but various thread lengths to encompass the size of the bone. Wires come In 1.8mm in diameter and come in 400mm overall lengths. They're meant for traction to the bone. These are inserted through or to the bone and attached to the frame to create a stable construction patient's limb thereby allowing the surgeon to correct or repair the patient's indications.

When used with other components this device stabilizes open and/or unstable fractures of long bones including intracapsular, intertrochanteric, supracondylar, or condylar. It is also used for joint fusions and limb lengthening of deformity corrections which involve cutting the bone. Revolution External Plating System is made from material that conforms to ASTM standards. The subject and predicate devices have nearly identical technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically the following characteristics are similar between the subject and predicates:

- Indications for Use
- Materials of manufacture
- Structural support mechanism

Table 5-1 Predicate Devices

510k Number	**Trade or Proprietary or Model Name**	**Manufacturer**	**Predicate Type**
K071394	SBi RingFIX™ System	Small Bone Innovations	Primary
K053472	Hoffmann® II MRI External Fixation System	Howmedical Osteonics Corp	Secondary
K152171	Orthofix TL-HEX True Lok Hexapod System (TL-HEX)	Orthofix Srl	Secondary
K970748	Taylor Spatial Frame External Fixation System	Smith & Nephew Inc.	Secondary
K112218	Ace-Fischer® External Fixation System	DePuy Orthopaedics, Inc.	Secondary
K031181	External Fixation Systems	Smith & Nephew, Inc.	Secondary
K140463	Integra External Fixation System	Ascension Orthopedics	Secondary

PERFORMANCE DATA

The following mechanical tests were completed on the subject device per ASTM F1541:

- Connector static axial grip testing
- Connector static torsion grip testing
- Ring static in-plane compression testing
- Strut static axial compression testing
- Construct dynamic axial compression testing

The results of this non-clinical testing show that the strength of the Revolution External Plating System is substantially equivalent to legally marketed predicate devices.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the Revolution External Plating System is substantially equivalent to the predicate device.