May 30, 2024

New Standard Device DBA Metalogix
% Danielle Besal
Principal Consultant
MRC Global
9085 E Mineral Circle
Suite 110
Centennial, Colorado 80112

Re: K233025
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: September 22, 2023
Received: September 22, 2023

Dear Danielle Besal:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lixin Liu -S

Lixin Liu, PhD
Assistant Director
DHT6A: Division of Joint Arthroplasty Devices
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233025

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.

510(k) Summary
Revolution External Plating System
K233025
May 30, 2024

Company: New Standard Device dba Metalogix
4766 Research Dr
San Antonio, TX 78240

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Company Contact: Ben Coburn
CEO | Metalogix
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Trade Name:	Revolution External Plating System
Common Name:	External fixation system
Classification:	Class II
Regulation Number:	21 CFR 888.3030 Single/multiple component metallic bone fixation appliances and accessories
Product Code:	KTT
Panel:	Orthopedic
Predicate Device:	K181630 Revolution External Plating System
Reference Device:	K152171 Orthofix TL-HEX True Lok Hexapod System

Device Description:
The Revolution External Plating System 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
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Substantial Equivalence Discussion:
The subject Revolution External Plating System is a modification to the predicate Revolution External Plating System (K181630) and includes design and material changes to individual system components and introduction of new welded tibial block constructs, connectors, and Z-post components. The subject system is similar in indications for use, materials, and design to the predicate system (K181630). Testing

has demonstrated that performance of the subject devices is equivalent to that of the predicate and the reference device, and thus, the differences in geometry versus the predicate do not raise different questions of safety and effectiveness.

Performance Testing:
Performance testing (ASTM F543, ASTM F1541, and torque to failure testing) was completed to support the modifications to the system and demonstrate its substantial equivalence to the predicate device.

Conclusion:
The subject Revolution External Plating System is substantially equivalent to the predicate Revolution External Plating System (K181630).