September 22, 2023

New Paradigm Biomedical
John Wixted
Co-Founder
163 Highland Ave #1144
Needham, Massachusetts 02494

Re: K230067
Trade/Device Name: Para-Fix External Fixation System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: LXT, KTT
Dated: December 21, 2022
Received: January 9, 2023

Dear John Wixted:

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/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 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 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, Ph.D.
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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K230067

Device Name

Para-Fix External Fixation System

Indications for Use *(Describe)*

The Para-Fix External Fixation System is intended to provide stabilization of open and/or unstable fractures and where tissue injury precludes the use of other fracture treatments such as IM rodding or casting.

The specific indications for the Para-Fix External Fixation System include:
- Bone fracture fixation
- Osteotomy
- Arthrodesis
- Correction of deformity
- Revision procedure where other treatments or devices have been unsuccessful
- Bone reconstruction procedures

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) #: K230067

510(k) Summary

Prepared on: 2023-09-21

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	New Paradigm Biomedical
Applicant Address	163 Highland Ave #1144 Needham, MA 02494 United States
Applicant Contact Telephone	1-781-549-9008
Applicant Contact	Mr. John Wixted
Applicant Contact Email	john.wixted@npbortho.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Para-Fix External Fixation System
Common Name	Single/multiple component metallic bone fixation appliances and accessories
Classification Name	Appliance, Fixation, Nail/Blade/Plate Combination, Multiple Component, Metal Composite
Regulation Number	888.3030
Product Code	LXT, KTT

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K051306	Hoffmann II MRI External Fixation System	LXT
K111786	Hoffmann 3 Modular External Fixation System	KTT

Device Description Summary

21 CFR 807.92(a)(4)

The New Paradigm Biomedical (NPB) Para-Fix External Fixation System is intended for use in external fixation of various long bone fractures, including tibial, femoral, pelvic, and humeral fractures in adults. The Para-Fix system consists of implants, frame components, & instrumentation for external fixation. The system features implants (Schanz Screws) in various diameters (Ø5 – 6mm) and lengths (120 – 300mm) to accommodate different anatomic sizes of patients. Schanz Screws are manufactured from medical grade stainless steel per ASTM F138. Para-Fix frame components include Clamps and Rods. Clamps are available in Combination (pin to rod, rod to rod) or Multi-Pin clamp styles. Clamps are manufactured from stainless steel. Ø11mm rods are available in lengths ranging from 65 – 500mm and are manufactured from carbon fiber. The Para-Fix system is provided non-sterile.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Para-Fix External Fixation System is intended to provide stabilization of open and/or unstable fractures and where tissue injury precludes the use of other fracture treatments such as IM rodding or casting.

The specific indications for the Para-Fix External Fixation System include:
- Bone fracture fixation
- Osteotomy
- Arthrodesis
- Correction of deformity
- Revision procedure where other treatments or devices have been unsuccessful

• Bone reconstruction procedures

Indications for Use Comparison 21 CFR 807.92(a)(5)

The indications for use of the subject device are consistent with those of the primary and secondary predicate external fixation systems.

Technological Comparison 21 CFR 807.92(a)(6)

The subject device has similar technological characteristics as the predicate devices. Subject and predicate/reference devices include implants manufactured from stainless steel in similar diameters and lengths. Subject and predicate devices include frame components consisting of clamps (manufactured from stainless steel in the subject device, material not disclosed in the primary predicate device), and rods manufactured from carbon fiber. Subject device rods are Ø11mm and primary predicate device rods are Ø8mm. The principles of operation are identical for subject and predicate devices.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Nonclinical (mechanical) testing per ASTM F1541-17 (Standard Specification and Test Methods for External Skeletal Fixation Devices) was performed by Element Materials Technology (Fairfield, OH) and NexTek Innovations (Logan, UT). The following tests were performed on subject and predicate/reference (Stryker Hoffmann II MRI and Stryker Apex Pin) devices: Static Axial Compression Connector Testing (ASTM F1541-17 A2), Static Axial Compression Subassembly Testing (ASTM F1541-17 A6), Static Torsion Full Construct Testing (ASTM F1541-17 A7), Static Axial Compression Testing Full Construct Testing (ASTM F1541-17 A7), and Fatigue (Multi-Cycle) Axial Compression/ Tension Full Construct Testing (ASTM F1541-17 A7).

Mechanical testing was performed according to ASTM F1541-17 and conclusively shows that the subject device performed substantially equivalent to the primary predicate device in all full construct test modalities. The subject device has been shown to be as safe and effective and perform as well as the primary predicate device.