July 29, 2020

S H Pitkar Orthotools Pvt Ltd
Vivek Mangalwedhekar
Head of Firm
Plot No. EL 32, J Block, MIDC Bhosari
Pune, Maharashtra 411026
INDIA

Re: K200518
Trade/Device Name: Pitkar External Fixation System - Rail Mechanism
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances and Accessories
Regulatory Class: Class II
Product Code: KTT, JDW
Dated: June 10, 2020
Received: June 16, 2020

Dear Vivek Mangalwedhekar:

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,

for Ting Song, Ph.D., R.A.C.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K200518

Device Name
Pitkar External Fixation System- Rail Mechanism

Indications for Use *(Describe)*

Pitkar External Fixation System- Rail Mechanism consist of Rail Fixation System and ALFA Fixator System. Their components are intended to be used on adult or pediatric patients as required.

A. Rail fixation System
1.Fracture fixation
2.For correcting diaphyseal deformities, metaphyseal deformities with or without shortenings
3.Correction of bony or soft tissue deformities
4.Limb Lengthening
5.For treating non-union and mal-union
6.Bone transport application

B. ALFA Fixator System
1.Open and closed fracture fixation
2.Fractures and disease which generally may result in joint contractures or loss of range of motion and fractures requiring distraction;
3.Pseudoarthrosis of long bones;
4.Limb lengthening;
5.Infected fractures or non-unions; and
6.Correction of long bone deformities.

Note: For Rail Fixation System and ALFA Fixator System
1. For Adult Assembly: Population to be adult males and females for given indications
2. For Pediatric Assembly: Population to be between age of 5 to 10 for given indications
3. It is recommended to avoid operating on children under the age of five, in case of pediatric application

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

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for Pitkar External Fixation System -Rail mechanism 510(k) premarket notification. The submission was prepared in accordance with the FDA guidance document, 'Format for Traditional and Abbreviated 510(k)s', issued on August 12, 2005.

1. Submitter:	S H Pitkar Orthotools Pvt Ltd. Plot No. EL 32, J Block, MIDC Bhosari Pune Maharashtra 411026 India
Contact Person:	Vivek Mangalwedhekar Head of Firm Telephone: +912040706464 Fax: +912046768107
Date:	10-July-2020
2. Device Name:	Pitkar External Fixation System- Rail Mechanism. The subject application has two devices covered that fall under Rail fixation category. Both the systems have Adult & Pediatric apparatus. Both the systems have different Rail design & clamps design. They are designated as: 1. Rail Fixation System 2. Alfa Fixator System Thus, there will be two subject devices for approval under this heading as both these systems have same application, device description, Indications, material composition etc.
Common or Usual Name:	Pitkar External Fixation System-Rail Mechanism
Classification Name:	Plates, Fixation, Bone Screws, Fixation, Bone
Product Code:	KTT- Single/multiple component metallic bone fixation appliances and accessories (21 CFR 888.3030) JDW -Smooth or threaded metallic bone fixation fastener (21 CFR 888.3040)
Regulatory Class:	II
5. Indications for Use:	Pitkar External Fixation System- Rail Mechanism consists of Rail Fixation System and ALFA Fixation System. Their components are intended to be used on adult or pediatric patients as required. A. Rail fixation System 1.Fracture fixation 2.For correcting diaphyseal deformities, metaphysical deformities with or without shortenings 3.Correction of bony or soft tissue deformities 4.Limb Lengthening 5.For treating non-union and mal-union

6.Bone transport application

B. ALFA Fixation System
1.Open and closed fracture fixation
2.Fractures and disease which generally may result in joint contractures or loss of range of motion and fractures requiring distraction;
3.Pseudoarthrosis of long bones;
4.Limb lengthening;
5.Infected fractures or non-unions; and
6.Correction of long bone deformities.

Note: For Rail Fixation System and ALFA Fixation System
1. For Adult Assembly: Population to be adult males and females for given indications
2. For Pediatric Assembly: Population to be between age of 5 to 10 for given indications
3. It is recommended to avoid operating on children under the age of five, in case of pediatric applications.

6. Summary of Technological Characteristics:

Design Features: The design features for Pitkar External Fixation System- Rail mechanism is similar to the primary predicate devices namely Orthofix Srl Orthofix Modulsystem – K955848 and secondary predicate device Smith & Nephew Rail System – K090926

Materials & Chemical Composition: Pitkar External Fixation System -Rail mechanism implants are single use and manufactured from implant grade stainless steels (per ASTM F138) which is commonly used materials in orthopedic implants. Appliances are single use and manufactured from Aluminium. Instruments are reusable and manufactured from Standard Specification For Wrought Stainless Steels For Surgical Instruments (ASTM F899 -2012) similar to the primary predicate devices namely Orthofix Srl Orthofix Modulsystem – K955848 and secondary predicate device Smith & Nephew Rail System – K090926

Sterilization: The implants, appliances and instruments are offered to the user in the non-sterile configuration. The non-sterile implants, appliances and instruments will be required to be steam sterilized by the user prior to use. The non- sterile packaging configuration is similar to the primary predicate devices namely Orthofix Srl Orthofix Modulsystem – K955848 and secondary predicate device Smith & Nephew Rail System – K090926

7. Summary of Performance Data: (Nonclinical and/or Clinical)

Non-Clinical Tests:

The device performance of Pitkar External Fixation System-Rail mechanism has been demonstrated against applicable standards ASTM F1541-02

- Axial Load test
- Torsion Test
- Fatigue test
- Cantilever Bending Test
- 4-Point Bending Test

Biocompatibility

Pitkar External Fixation System-Rail Mechanism is comprised of the same material and have the same manufacturing, body contact, and sterilization properties as other commercially available devices and materials with a long history of clinical use in orthopedic implants. Therefore, Pitkar External Fixation System-Rail Mechanism meets the ISO 10993-1 standard requirements for biocompatibility and no further characterization testing is required.

8. Conclusion:

From the data available, we can justify that Pitkar External Fixation System is-Rail mechanism safe as effective and perform as same indications for use as that of already marketed predicate devices identified in point 3 of 510(k) summary i.e Orthofix Srl– Orthofix Modulsystem– K955848 and Smith & Nephew Rall System – K090926

Hence Pitkar External Fixation System- Rail mechanism can be considered safe and effective for intended use.