January 14, 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: K190486
Trade/Device Name: Pitkar 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: KTT
Dated: July 13, 2019
Received: July 18, 2019

Dear Vivek Mangalwedhekar:

This letter corrects our substantially equivalent letter of October 16, 2019.

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,

Ting Song -S

Ting Song
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)*

K190486

Device Name

Pitkar External Fixation System

Indications for Use *(Describe)*

The Pitkar External Fixation System is indicated for both adults and pediatric patients for:

1. Open and closed fracture fixation
2. Pseudoarthrosis or non-union of long bones
3. Limb lengthening by epiphyseal or metaphyseal distraction
4. Correction of bony or soft tissue deformities
5. Correction of segmental or nonsegmental bony or soft tissue defects
6. Post-Traumatic joint contracture which has resulted in loss of range of motion

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 the Pitkar External Fixation System 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.

Sponsor:

S H Pitkar Orthotools Pvt Ltd.
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India

Contact Person:

Vivek Mangalwedhekar
Head of Firm
Telephone: +912040706464
Fax: +912046768107

Date:

15 July 2019

Subject Device:

Trade Name: Pitkar External Fixation System

Classification Name:

- 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)

Predicate Device(s):

K083789	ACE-Fischer External Fixation System	DePuy Orthopaedics
K970748	Taylor Spatial Frame	Smith & Nephew, Inc.

Purpose and Device Description:

The purpose of this submission is to request clearance for the new Pitkar External Fixation System. The implantable components are manufactured from Stainless Steel per ASTM F899. The system will be provided in non-sterile configuration and will require steam sterilization prior to use.

Intended Use and Indications for Use:

The Pitkar External Fixation System is indicated for both adults and pediatric patients for:

1. Open and closed fracture fixation
2. Pseudoarthrosis or non-union of long bones
3. Limb lengthening by epiphyseal or metaphyseal distraction
4. Correction of bony or soft tissue deformities
5. Correction of segmental or nonsegmental bony or soft tissue defects
6. Post-Traumatic joint contracture which has resulted in loss of range of motion

Summary of Technological Characteristics:

The rationale for substantial equivalence is based on consideration of the following characteristics:

- **Intended Use:** The intended use is similar to the intended use of the predicate systems.
- **Indications for Use:** The indications for use are similar to the indications for use cleared in predicate systems.
- **Materials:** The new Pitkar Extremal Fixation System implants are manufactured from Stainless Steel (per ASTM F899). Implant grade stainless steels are commonly used materials in orthopedic implants.
- **Design Features:** The design features for new Pitkar External Fixation System is similar to those in currently marketed predicate devices. The design differences have not identified any issues that would impact the safety and effectiveness of the device.
- **Sterilization:** The system is offered to the user in non-sterile configuration and will required to be steam sterilized by the user prior to use. The non-sterile packaging configuration is similar to the predicate devices currently marketed.

Summary of Performance Data (Nonclinical and/or Clinical)

- **Non-Clinical Tests:**
    - ASTM F1541-02 “Standard Specification and Test Methods for External Skeletal Fixation Devices”

- **Clinical Tests:**
  - N/A

Substantial Equivalence Conclusion

The Pitkar External Fixation System has shown to be substantially equivalent to the predicate devices. Results of the non-clinical tests indicate that the device will perform within the intended uses and no new issues of safety and effectiveness have been raised.