October 6, 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: K200728
Trade/Device Name: Pitkar Sixafix 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, OSN
Dated: September 1, 2020
Received: September 8, 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,

Ting Song -S

Ting Song, Ph.D., R.A.C.
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

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 Sixafix 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.

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:	05-October-2020
2. Device Name:	Pitkar Sixafix System
Common or Usual Name:	Pitkar Sixafix System
Classification Name:	Single/multiple component metallic bone fixation appliances and accessories (21 CFR 888.3030)
Product Code:	KTT, OSN
Regulatory Class:	II
3. Predicate Device(s):	Smith & Nephew Inc.- Taylor Spatial Frame -K 970748
4. Device Description:	The purpose of this submission is to request clearance for the new Pitkar Sixafix System. The Pitkar Sixafix System includes a web based software that is designed to assist the physician in performing precise deformity or fracture reduction and should always be used with hardware. The Sixafix System software receives inputs from measurements taken by the physician and produces outputs recommending adjustments to the fixator that define a correction path for the deformity. To guide the surgeon, detailed information is provided in Software manual. The implantable components are manufactured from Stainless Steel per ASTM F138. The system will be provided in non-sterile configuration and will require steam sterilization prior to use.
5. Indications for Use:	The Pitkar Sixafix System is indicated for the following treatments in adults, and in both children (3-12) and adolescents (12-21) in which the growth of plates have fused or will not be the crossed with the hardware • Open and closed fracture fixation • Pseudoarthrosis or non-union of long bones

- Limb lengthening by epiphyseal or metaphyseal distraction
- Correction of bony or soft tissue deformities
- Correction of segmental or nonsegmental bony or soft tissue defects
- Post-Traumatic joint contracture which has resulted in loss of range of motion

6. Summary of Technological Characteristics:

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

Design Features: The design features for the Pitkar Sixafix System is similar to predicate devices namely Smith & Nephew Inc.- Taylor Spatial Frame -K 970748

Materials & Chemical Composition: The Pitkar Sixafix System 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 predicate devices namely Smith & Nephew Inc.- Taylor Spatial Frame -K 970748

Sterilization: The implants and instruments are offered to the user in the non-sterile configuration. The non-sterile implants and instruments will be required to be steam sterilized by the user prior to use. The non- sterile packaging configuration is similar to the predicate device Smith & Nephew Inc.- Taylor Spatial Frame -K 970748

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

Non-Clinical Tests:

1. Software Verification and Validation per FDA's guidance document titled "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"
2. ASTM F1541-02 "Standard Specification and Test Methods for External Skeletal Fixation Devices"
   - Four point bend test
   - Cantiliver bent test A-P plane
   - Cantiliver bent test L-M plane
   - Axial load test
   - Torsion test
   - Fatigue test

Biocompatibility

The Pitkar Sixafix System 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, the Pitkar Sixafix System meets the ISO 10993-1 standard requirements for biocompatibility and no further characterization testing is required.

8. Conclusion:

The comparisons of indications for use and technological characteristics with the predicate device and the performance data demonstrate that the Pitkar SixaFix System is substantially equivalent to the legally marketed predicate devices identified in point 3 of 510(k) summary i.e Smith & Nephew Inc.- Taylor Spatial Frame -K 970748

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)*

K200728

Device Name
Pitkar Sixafix System

Indications for Use *(Describe)*

Pitkar Sixafix System is indicated for the following treatments in adults, and in both children (3-12) and adolescents (12-21) in which the growth of plates have fused or will not be the crossed with the hardware.

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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