February 27, 2020

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

Re: K192619
Trade/Device Name: Pitkar Locked 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: HRS, HWC
Dated: September 15, 2019
Received: September 23, 2019

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,

Shumaya Ali, MPH
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma 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)*

K192619

Device Name
Pitkar Locked Plating System

Indications for Use *(Describe)*

Pitkar Locked Plating System is indicated for fixation of fractures, osteotomies and non-unions of various bones including the humerus, radius, ulna, femur, tibia, fibula and clavicle, including in osteopenic bone.

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 Locked Plating 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:	27-Feb-20
2. Device Name:	Pitkar Locked Plating System
Common or Usual Name:	Orthopedic Bone Plate Orthopedic Bone Screw
Classification Name:	Plates, Fixation, Bone Screws, Fixation, Bone
Product Code:	HRS- Single/multiple component metallic bone fixation appliances and accessories (21 CFR 888.3030) HWC -Smooth or threaded metallic bone fixationfastener (21 CFR 888.3040)
Regulatory Class:	II
3. Primary Predicate Device(s):	CARE BRAND Locking Bone Plate and Screws Osteosynthesis Plating System - K153374
Other Predicate Devices :	SYNTHES LCP Distal Tibia Plates – K013248 SYNTHES LCP Proximal Tibia Plate - K030597 SYNTHES LCP Distal Femur Plates – K062564 SYNTHES LCP Distal Humerus Plates - K033995 SYNTHES LCP Proximal Humerus Plates – K011815 SYNTHES Locking Distal Radius Plating System– K012114 SYNTHES LCP Clavicle Plate System – K073186

4. Device Description:

The purpose of this submission is to request clearance for the new Pitkar Locked Plating System. The Pitkar Locked Plating System implants are designed to address fractures of the humerus, radius, ulna, femur, tibia, fibula, and clavicle. The system is comprised of plates, screws and instruments to facilitate the installation of the implants. The plates and screws are manufactured from Titanium Alloy per ASTM F136. Implants and instruments will be provided in non-sterile configuration and will require steam sterilization prior to use.

5. Indications for Use:

The Pitkar Locked Plating System is indicated for fixation of fractures osteotomies and non-unions of various bones including the humerus, radius, ulna femur, tibia, fibula, and clavicle, including osteopenic bone.

6. Summary of Technological Characteristics and comparison to predicate device

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

Design Features: The design features for the Pitkar Locked Plating System is similar to the Primary predicate system device- CARE BRAND Locking Bone Plate and Screws Osteosynthesis Plating System - K153374

Materials & Chemical Compostion: The Pitkar Locked Plating System plates and screws are manufactured from Titanium Alloy (per ASTM F136). Implant grade titanium alloys are commonly used materials in orthopedic implants & instruments are manufactured from Standard Specification For Wrought Stainless Steels For Surgical Instruments (ASTM F899 -2012) similar to the Primary predicate system device- CARE BRAND Locking Bone Plate and Screws Osteosynthesis Plating System - K153374

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 Primary predicate devices - CARE BRAND Locking Bone Plate and Screws Osteosynthesis Plating System - K153374

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

Non-Clinical Tests:
The device performance of Pitkar Locked Plating System has been demonstrated against following applicable standards

- ASTM F 382
- ASTM F 384
- ASTM F 543

For Bone Plates as per ASTM F 382 & ASTM F 384

- Static Four Point Bend Test
- Dynamic Four Point Bend Test

For Bone Screws as per ASTM F 543

- Torsional Properties
- Driving Torque
- Pull-Out test

Biocompatibility:
Pitkar Locked Plating System devices are 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 Locked Plating System devices 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 the Pitkar Locked Plating System is 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 Primary predicate devices CARE BRAND Locking Bone Plate and Screws Osteosynthesis Plating System - K153374

Hence Pitkar Locked Plating System can be considered safe and effective for inteded use.