September 1, 2023

Intrauma S.p.A
Stefano Pullega
Quality and Regulatory Director
Via Genova 19
Rivoli (TO), 10098
Italy

Re: K230623
Trade/Device Name: KITE Distal Fibula Kit
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: August 3, 2023
Received: August 3, 2023

Dear Stefano Pullega:

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,

FDA Tejen D. Soni -S

For
Shumaya Ali, M.P.H.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K230623

Device Name
KITE Distal Fibula Kit

Indications for Use *(Describe)*

The KITE Distal Fibula Kit is indicated for:
- Diaphyseal and metaphyseal fractures of the distal fibula
- Intra and extra articular fractures of the distal fibula
- Non-unions of the distal fibula

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

510(k) Number	K230623
Device Trade Name:	KITE Distal Fibula Kit
Manufacturer:	Intrauma S.p.A. Via Genova, 19 Rivoli (TO) Italy 10098
Primary Contact:	Stefano Pullega Quality and Regulatory Director Intrauma S.p.A. Via Genova 19 Rivoli (TO) Italy 10098 Office: +39.011.9539496 Mobile: +39.344.3488351 stefano.pullega@intrauma.com
Prepared by:	MCRA, LLC 803 7th Street, NW, 3rd Floor Washington, DC 20001 Office: 202.552.5800
Date Prepared:	August 30, 2023
Classifications:	21 CFR 888.3030, Bone Fixation Plate (Primary) 21 CFR 888.3040, Screw Fixation Bone
Class:	II
Product Codes:	HRS, HWC
Primary Predicate:	Synthes 2.7mm/3.5mm LCP Distal Fibula Plate (K073460)
Additional Predicates:	Synthes Small Fragment Dynamic Compression Locking (DCL) System (K000684), and Baby Gorilla®/Gorilla® Plating System (K203511)

Indications For Use:

The KITE Distal Fibula Kit is indicated for:

- Diaphyseal and metaphyseal fractures of the distal fibula
- Intra and extra articular fractures of the distal fibula
- Non-unions of the distal fibula

Device Description:
The KITE Distal Fibula Kit is intended for the stabilization of distal lateral and posterior fibular fractures including those of the diaphysis and metaphysis and intra- and intra-articular fractures. The system is comprised of various plates and screws which allow it to be customized to a patient's anatomy and fracture pattern. The plate is secured in place via autolocking and cortical screws.

Predicate Device:
Intrauma S.p.A. submits the following information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, KITE Distal Fibula Plate is substantially equivalent in indications, design principles, and performance to the following predicate devices, which have been determined by FDA to be substantially equivalent to pre-amendment devices:

Primary Predicate: Synthes 2.7mm/3.5mm LCP Distal Fibula Plate (K073460)
Additional Predicates: Synthes Small Fragment Dynamic Compression Locking (DCL) System (K000684), and Baby Gorilla®/Gorilla® Plating System (K203511)

Performance Testing Summary:
Static 4-point bending tests were performed on the subject plates in order to measure the bending stiffness, the bending structural stiffness, and the bending strength using a 4-Point Bending test according to ASTM F382-17 Annex A1. Testing of the subject plates was also compared to acceptance criteria from the "Orthopedic Fracture Fixation Plates - Performance Criteria for Safety and Performance Based Pathway" to support subject device safety and performance.

The screws were tested according to ASTM F543-17 and results from testing were compared to acceptance criteria from the FDA Guidance Document "Orthopedic Non-Spinal Metallic Bone Screws and Washers – Performance Criteria for Safety and Performance Based Pathway" to support subject device safety and performance. The following tests were performed for each screw type included in the KITE Distal Fibula Kit:

- Torsional Test
- Insertion and Removal Test
- Pullout Test
- Self-Tapping Test

Additionally, LAL testing was performed on the KITE Distal Fibula Kit according to FDA Guidance document "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile Guidance for Industry and Food and Drug Administration Staff" issued January 21, 2016.

Substantial Equivalence:
The KITE Distal Fibula Kit is substantially equivalent to the predicate devices with respect to indications, design, function, and performance. Additionally, the KITE Distal Fibula Kit is substantially equivalent to the additional predicates with respect to the full size range and types of plates and screws offered.

Technological Comparison

The subject and predicate devices use the same inherent technology (i.e., screw and plate components) to fix bone fragments to allow for bone healing in the distal fibula. The subject and

predicate devices are comprised of both locking and cortical screws to achieve bone fixation of the plate. The plates contain various quantities and types of holes specific to each size offering for use with the included bone screws.

Conclusion:

The subject and predicate devices have the same intended use, have similar technological characteristics, and are made of similar materials. The subject and predicate devices are packaged in similar materials and are sterilized using similar methods. The performance data included in this submission demonstrate substantial equivalence to the predicate device listed above. Additionally, performance testing data collected on the subject device demonstrate alignment acceptance criteria within FDA guidance documents. Therefore, the KITE Distal Fibula Plate is substantially equivalent to the predicate devices.