March 11, 2022

Intai Technology Corporation
Dale Chang
Head of Implant Business Unit
No. 9 Jingke Rd., Nantun Dist.
Taichung, Taichung 40852
Taiwan

Re: K201229
Trade/Device Name: Intai Anatomic Locking Plate and Screw 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: April 14, 2020
Received: May 7, 2020

Dear Dale Chang:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K201229

Device Name
Intai Anatomical Locking Plate and Screw System

Indications for Use *(Describe)*
The Intai Anatomy Locking Plate and Screw System is provided non-sterile.
The system is intended for use in fixation of fractures to the various bones, including: clavicle, radius, ulna, humerus, femur, tibia, fibula, and acetabulum for adults.
This system is not indicated for use in the spine.

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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Intai Technology Corp.
No.9 Jingke Rd., Nantun District,
Taichung City 408, Taiwan, R.O.C

K201229 - 510(k) SUMMARY

This summary regarding 510(k) information is being submitted in accordance with the requirements of 21 CFR 807.92.

Submitted By	Intai Technology Corp. Registration No.3011187779 No.9 Jingke Rd., Nantun District, Taichung City, Taiwan, R.O.C. Tel. +886 4 23595336 Fax.+886 4 36013076
Contact Person	Kevin Wang
Date Prepared	March 11th, 2022
Device Name	Intai Anatomical Locking Plate and Screw System
Classifications	Class II, 21 CFR 888.3030 - Single/multiple component metallic bone fixation appliances and accessories. (primary) Class II, 21 CFR 888.3040 - Smooth or threaded metallic bone fixation fastener.
Product Codes	HRS (primary), HWC

Predicate Devices Information

The device is substantially equivalent to the marketed:

Primary Predicate Device			
No.	**Premarket Notification Number**	**Name**	**Device Name**
013	K092609	Synthes	3.5mm/4.5mm Curved Narrow and Broad Locking Compression Plates (LCP)
Other Predicate Devices			
001	K073186	Synthes	3.5mm LCP Clavicle Plate System
002	K061753	Synthes	Clavicle Hook Plate
003	K040022	Stryker Leibinger	Universal Distal Radius System
004	K082078	Zimmer	Periarticular Locking Plate System: Distal Humeral and Proximal Ulna Plate
005	K041860	Synthes	LCP® Proximal Humerus Plates, Long
006	K082078	Zimmer	Periarticular Locking Plate System: Distal Humeral and Proximal Ulna Plate
007	K030597	Synthes	3.5mm Titanium LCP Proximal Tibia Plate
008	K013248	Synthes	LCP Distal Tibia Plate
009	K073460	Synthes	2.7 mm/ 3.5 mm LCP Distal Fibula Plates
010	K062564	Synthes	Synthes LCP Distal Femur Plates
011	K033805	Synthes	3.5mm/4.5mm LCP Metaphyseal Plate
012	K093928	Synthes	3.5 mm Quadrilateral Surface Plates
014	K042377	Synthes	Low Profile Reconstruction Plates
015	K043185	Synthes	3.5mm Cortex Screw

	016	K060710	Zimmer	Universal Locking System, 3.5mm Plates And Screws-4936 Plates,4835 Screws

Material	Titanium-alloy per ASTM F136 or Stainless Steel per ASTM F138/F139
Device Description	The Intai Anatomical Locking Plate and Screw System offers anatomically contoured plates for use with non-locking and locking screws. The plates are provided with locking holes as well as holes for cortex screws to enhance compression pressure. With the combination of locking and compression technology, the system further ensures the stability of the implant devices.
Indication for use	The Intai Anatomy Locking Plate and Screw System is provided non-sterile. The system is intended for use in fixation of fractures to the various bones, including: clavicle, radius, ulna, humerus, femur, tibia, fibula, and acetabulum for adults.This system is not indicated for use in the spine.
Summary of Technological Characteristics:	The subject device and the predicate devices have the same intended use and have the same or similar technological characteristics. The subject and predicate devices are all fabricated from the same or similar materials and share similar design characteristics. Any differences in the technological characteristics do not raise new issues of safety or efficacy. ● **Intended Use:** Both the subject and predicate devices are intended for use in fixation fracture of bones. ● **Materials:** Use similar material. -Stainless Steel -Titanium Alloy ● **Design Features:** Both the subject and predicate devices include Locking Compression Plates.
Performance Data (Non-clinical) discussion	Performance of the Intai Anatomical Locking Plate and Screw System has been demonstrated substantial equivalence through the test parameters outlined in ASTM F382 to conduct Single Cycle Bend and Bending fatigue testing. In addition, Torsional Properties, Driving Torque, and Axial Pullout testing was conducted on the screws per ASTM F543.
Conclusion	The subject device has been compared to the predicate devices with respect to intended use, materials, design features, and non-clinical tests. The technological characteristics of the subject device do not raise new type of questions regarding safety and efficacy. These comparison demonstrate that the Intai Anatomical Locking Plate and Screw System is substantially equivalence to the predicate devices.