August 24, 2023

A Plus Biotechnology Co., Ltd
Frank Hsu
Official Correspondent
2F-2, No. 120, Qiaohe Rd., Zhonghe Dist.
New Taipei City, 23584
Taiwan

Re: K223150
Trade/Device Name: APS Metal Plate & Screw System
Regulation Number: 21 CFR 888.3030
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: August 21, 2023
Received: August 21, 2023

Dear Frank Hsu:

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)*
K223150

Device Name
APS Metal Plate & Screw System

Indications for Use *(Describe)*

Locking Screw:
The locking screws, in combination with the appropriate locking plate, are indicated for fixation of fractures, osteotomies, non-unions, replantations, and fusions of small bones and small bone fragments, particularly in osteopenic bone of the hand, wrist, foot, and ankle.

Cortex Screw:
The Cortex Screw is indicated to be used with the APS Metal Plate & Screw System for the fixation of fractures, osteotomies, non-unions, replantations, and fusions involving small bones and bone fragments, especially in osteopenic conditions. Examples include, but are not limited to, the hand, wrist, foot, and ankle.

Star Cancellous Screw:
The Star Cancellous Screw is indicated for the fixation of fractures, osteotomies, and non-unions involving the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, and distal tibia, fibula, particularly in osteopenic bone.

APS HLR Screw:
The APS HLR Screw is indicated for fracture fixation, reconstruction, osteotomy, and arthrodesis of various bones and bone fragments, including joint fusions (arthrodesis) in the foot and fixation of intra-articular fractures of the humerus, femur, and tibia.

Distal CAS Locking Plate:
The Distal CAS Locking Plate is indicated for fixation of fractures, malunions, non-unions, and osteotomies of the distal (lateral) clavicle.

Distal Clavicle Hook Locking Plate | Clavicle Anatomical Midshaft Locking Plate:
The Distal Clavicle Hook Locking Plate and Clavicle Anatomical Midshaft Locking Plate are indicated for the fixation of distal (lateral) clavicle fractures, mid-shaft clavicle fractures, and dislocations of the acromioclavicular joint.

Distal Medial Humeral Locking Plate | Proximal Humeral Locking Plate:
The Distal Medial Humeral Locking Plate and Proximal Humeral Locking Plate are indicated for fractures and fracture dislocations, osteotomies, and non-unions of the distal (medial) and proximal humerus, particularly in osteopenic bone.

Small ABS Locking Plate | Dynamic Compression Locking Plate:
The Small ABS Locking Plate and Dynamic Compression Locking Plate are indicated for fixation of fractures, osteotomies, and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia, fibula, particularly in osteopenic bone.

Distal Radial Locking Plate | Trident Distal Radial Locking Plate:
The Distal Radial Locking Plate and Trident Distal Radial Locking Plate are indicated for fixation of complex intra- and extra-articular fractures and osteotomies of the distal radius and other small bones.

Distal Lateral Femoral Locking Plate:
The Distal Lateral Femoral Locking Plate is indicated for buttressing multi-fragmentary distal femur fractures, including supracondylar, intra-articular and extra-articular condylar, peri-prosthetic fractures, and fractures in normal or osteopenic

bone, non-unions and mal-unions, and osteotomies of the femur.

Large ABS Locking Plate:
The Large ABS Locking Plate is indicated for fixation of various long bones, such as the humerus, femur, and tibia. It is also for use in the fixation of osteopenic bone and fixation of non-unions or mal-unions.

Distal FDH Locking Plate:
The Distal FDH Locking Plate is indicated for fractures, osteotomies, and non-unions of the metaphyseal and diaphyseal region of the distal fibula, especially in osteopenic bone.

Distal Tibia Locking Plate System (Antero Lateral Distal Tibial Locking Plate, Distal Medial Tibial Locking Plate):
The Distal Tibia Locking Plate System is indicated for fractures, osteotomies, and non-unions of the distal tibia, especially in osteopenic bone.

Proximal Medial Tibial Locking Plate:
The Proximal Medial Tibial Locking Plate is indicated for buttressing metaphyseal fractures of the medial tibial plateau, split-type fractures of the medial tibial plateau, and medial split fractures with associated depression fractures of the medial tibial plateau.

Calcaneal Locking Plate:
The Calcaneal Locking Plate is indicated for addressing complex fractures and osteotomies of the calcaneus, including, but not limited to, extra-articular, intra-articular, joint depression, tongue-type, and severely comminuted fractures.

Distal RAF Locking Plate:
The Distal RAF Locking Plate is indicated for fixation of complex intra- and extra-articular fractures and osteotomies of the distal radius and other small bones.

Mini Locking Plate System:
The Mini Locking Plate System is indicated for fixation of fractures, osteotomies, non-unions, replantations, and fusions of small bones and small bone fragments, particularly 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.

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

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510(k) SUMMARY
APS Metal Plate & Screw System

Submitter	A PLUS BIOTECHNOLOGY COMPANY LIMITED 2F-2, No. 120, Qiaohe Rd., Zhonghe Dist. New Taipei City, TAIWAN Contact Person: Frank Hsu TEL: +886-2-22499222 ext.710 Email: frank.hsu@aplusbio.com
Date prepared	August 10, 2023
Name and Classification	Trade Name: APS Metal Plate & Screw System Classification Name: Single/Multiple Component Metallic Bone Fixation Appliances and Accessories (Primary), Smooth or Threaded Metallic Bone Fixation Fastener Classification Number: 21 CFR 888.3030 (Primary), 21 CFR 888.3040 Regulatory Class: II Product Code: HRS (Primary), HWC

APS Metal Plate & Screw System	
Primary Predicate Device	SYNTHES (USA) LCP PROXIMAL HUMERUS PLATES, LONG (K041860)
Additional Predicate	SYNTHES LARGE FRAGMENT DYNAMIC COMPRESSION LOCKING (DCL) SYSTEM (K000682) SMALL FRAGMENT DYNAMIC COMPRESSION LOCKING (DCL) SYSTEM (K000684) SYNTHES (USA) MEDIAL DISTAL TIBIA PLATES (K001945) SYNTHES LOCKING DISTAL RADIUS PLATING SYSTEM (K012114) SYNTHES LCP DISTAL TIBIA PLATES (K013248) SYNTHES 3.5MM TITANIUM LCP PROXIMAL TIBIA PLATES (K030597) SYNTHES (USA) 3.5/4.5MM LCP MEDIAL PROXIMAL TIBIA PLATES (K032269) SYNTHES (USA) CLAVICLE HOOK PLATES (K061753) SYNTHES LCP DISTAL FEMUR PLATES (K062564) SYNTHES (USA) MODULAR MINI FRAGMENT LCP SYSTEM

	(K063049) SYNTHES 3.5MM LCP CLAVICLE PLATE SYSTEM (K073186) SYNTHES 2.7 MM/3.5 MM LCP DISTAL FIBULA PLATES (K073460) SYNTHES (USA) 2.4 MM VA-LCP TWO COLUMN VOLAR DISTAL RADIUS PLATES (K083694) SYNTHES (USA) 1.5MM MINI FRAGMENT LCP SYSTEM (K090047) SYNTHES (USA) 2.4MM LCP VOLAR COLUMN DISTAL RADIUS PLATES (K091644) SYNTHES 2.7MM AND 3.5MM VARIABLE ANGLE LCP MIDFOOT/HINDFOOT SYSTEM (K131186) Acutrak System, Acutrak 2 System (K944330)

APS Metal Plate & Screw System	Device Description
	The APS Metal Plate & Screw System provides anatomically contoured plates designed for use with both non-locking and locking screws. These plates are equipped with locking holes as well as holes for cortex screws, enhancing compression pressure. The combination of locking and compression technologies ensures the implants provide sufficient stability.

* The system is provided non-sterile and is sterilized in the user facility.

Indications For Use

Locking Screw:

The locking screws, in combination with the appropriate locking plate, are indicated for fixation of fractures, osteotomies, non-unions, replantations, and fusions of small bones and small bone fragments, particularly in osteopenic bone of the hand, wrist, foot, and ankle.

Cortex Screw:

The Cortex Screw is indicated to be used with the APS Metal Plate & Screw System for the fixation of fractures, osteotomies, non-unions, replantations, and fusions involving small bones and bone fragments, especially in osteopenic conditions. Examples include, but are not limited to, the hand, wrist, foot, and ankle.

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The APS HLR Screw is indicated for fracture fixation, reconstruction, osteotomy, and arthrodesis of various bones and bone fragments, including joint fusions (arthrodesis) in the foot and fixation of intra-articular fractures of the humerus, femur, and tibia.

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Distal Clavicle Hook Locking Plate | Clavicle Anatomical Midshaft Locking Plate:
The Distal Clavicle Hook Locking Plate and Clavicle Anatomical Midshaft Locking Plate are indicated for the fixation of distal (lateral) clavicle fractures, mid-shaft clavicle fractures, and dislocations of the acromioclavicular joint.

Distal Medial Humeral Locking Plate | Proximal Humeral Locking Plate:
The Distal Medial Humeral Locking Plate and Proximal Humeral Locking Plate are indicated for fractures and fracture dislocations, osteotomies, and non-unions of the distal (medial) and proximal humerus, particularly in osteopenic bone.

Small ABS Locking Plate | Dynamic Compression Locking Plate:
The Small ABS Locking Plate and Dynamic Compression Locking Plate are indicated for fixation of fractures, osteotomies, and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia, fibula, particularly in osteopenic bone.

Distal Radial Locking Plate | Trident Distal Radial Locking Plate:
The Distal Radial Locking Plate and Trident Distal Radial Locking Plate are indicated for fixation of complex intra- and extra-articular fractures and osteotomies of the distal radius and other small bones.

Distal Lateral Femoral Locking Plate:

The Distal Lateral Femoral Locking Plate is indicated for buttressing multi-fragmentary distal femur fractures, including supracondylar, intra-articular and extra-articular condylar, peri-prosthetic fractures, and fractures in normal or osteopenic bone, non-unions and mal-unions, and osteotomies of the femur.

Large ABS Locking Plate:
The Large ABS Locking Plate is indicated for fixation of various long bones, such as the humerus, femur, and tibia. It is also for use in the fixation of osteopenic bone and fixation of non-unions or mal-unions.

Distal FDH Locking Plate:
The Distal FDH Locking Plate is indicated for fractures, osteotomies, and non-unions of the metaphyseal and diaphyseal region of the distal fibula, especially in osteopenic bone.

Distal Tibia Locking Plate System (Antero Lateral Distal Tibial Locking Plate, Distal Medial Tibial Locking Plate):
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Proximal Medial Tibial Locking Plate:
The Proximal Medial Tibial Locking Plate is indicated for buttressing metaphyseal fractures of the medial tibial plateau, split-type fractures of the medial tibial plateau, and medial split fractures with associated depression fractures of the medial tibial plateau.

Calcaneal Locking Plate:
The Calcaneal Locking Plate is indicated for addressing complex fractures and osteotomies of the calcaneus, including, but not limited to, extra-articular, intra-articular, joint depression, tongue-type, and severely comminuted fractures.

Distal RAF Locking Plate:
The Distal RAF Locking Plate is indicated for fixation of complex intra- and extra-articular fractures and osteotomies of the distal radius and other small bones.

Mini Locking Plate System:
The Mini Locking Plate System is indicated for fixation of fractures, osteotomies,

non-unions, replantations, and fusions of small bones and small bone fragments, particularly in osteopenic bone.

Comparison of Technological Characteristics with The Predicate Device:
Screw system: The subject and predicate devices have similar technological characteristics and the minor differences do not raise any new questions of safety and effectiveness. Specifically, the following characteristics are similar between the subject and predicates:
-Indications for Use
-Operation technique
-Use of a temporary implant to secure tissue
The following technological differences exist between the subject and predicate devices:
-Materials of Manufacture (Subject implantable devices are manufactured from Ti6Al4V per ASTM F136, predicate devices are manufactured from pure titanium per ASTM F67)

Plate system: The subject and predicate devices have similar technological characteristics and the minor differences do not raise any new questions of safety and effectiveness. Specifically, the following characteristics are similar between the subject and predicates:
-Indications for Use
-Operation technique
-Use of a temporary implant to secure tissue
The following technological differences exist between the subject and predicate devices:
-Materials of Manufacture (Subject implantable devices are manufactured from Ti6Al4V per ASTM F136, predicate devices are manufactured from Ti6Al7Nb per ASTM F136)

PERFORMANCE DATA
Biocompatibility testing
The biocompatibility evaluation for the APS Metal Plate & Screw System was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The

compatibility between the materials used and biological tissues, cells and body fluids is tested by Biocompatibility Lab. of LEON Biotech. Co., Ltd. and meet the requirements of performance standard.
The raw material of all system conforms to ASTM F136 for chemical composition.

Mechanical testing

Mechanical testing which established equivalency included ASTM F543 and ASTM F382. Therefore, the subject device is as safe and effective as the legally marketed predicate device.

CONCLUSIONS:

The overall technology characteristics and mechanical performance data lead to the conclusion that the APS Metal Plate & Screw System is substantially equivalent to the predicate devices.