March 17, 2026

A Plus Biotechnology Co., Ltd.
Helen Chan
R&D assistant Manager
3f., # 23, Qiaohe Rd., Zhonghe Dist.
New Taipei City, 23529
Taiwan

Re: K254053
Trade/Device Name: APS Spear Locking Plate 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: December 17, 2025
Received: December 17, 2025

Dear Helen Chan:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Christopher Ferreira, M.S.
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K254053

Please provide the device trade name(s).

APS Spear Locking Plate System

Please provide your Indications for Use below.

The APS Spear Locking Plate System is indicated for use in small bone reconstruction, corrective osteotomies, and fracture fixation.

2.4mm Locking Screw
The 2.4mm Locking Screw is intended for use with the Spear Locking Plate in metacarpal and metatarsal reconstruction, corrective osteotomies, and fracture fixation.

2.7mm Continuous Locking Screw
The 2.7mm Continuous Locking Screw is intended for use with the Spear Locking Plate, for fixation and compression at the osteotomy or fracture site. It is suitable for metacarpal and metatarsal corrective osteotomies and fracture stabilization.

Spear Locking Plate
The Spear Locking Plate is intended for use in metacarpal and metatarsal reconstruction, corrective osteotomies, and fracture fixation.

Spear Locking Plate II
The Spear Locking Plate II is intended for metacarpal and metatarsal reconstruction, corrective osteotomies, and fracture fixation.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: **K254053**

510(k) Summary

Prepared on: 2026-03-17

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	A Plus Biotechnology Co., Ltd.
Applicant Address	3F., No. 23, Qiaohe Rd., Zhonghe Dist. New Taipei City 23529 Taiwan
Applicant Contact Telephone	+886-2-22499222
Applicant Contact	Mrs. Helen Chan
Applicant Contact Email	aplus.helen.chan@gmail.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	APS Spear Locking Plate System
Common Name	Single/multiple component metallic bone fixation appliances and accessories
Classification Name	Appliance, Fixation, Nail/Blade/Plate Combination, Multiple Component
Regulation Number	888.3030
Product Code(s)	HRS, HWC

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K101962	Mini MaxLock Extreme Plating System	HRS
K033975	SYNTHES 2.4 MM TITANIUM (TI.) LOCKING SCREWS	HWC

Device Description Summary

21 CFR 807.92(a)(4)

The APS Spear Locking Plate System (2.4mm locking screw (0824-4302-xx); 2.7mm continuous locking screw (0827-2302-xx); Spear locking plate (1300-0x05-xx); and Spear locking plate ii (1301-0x05-xx)) is an internal fixation device consisting of anatomically contoured titanium plates and associated locking screws, designed for use in small bone reconstruction, corrective osteotomies, and fracture fixation. The system functions by engaging locking screws into threaded plate holes, forming a fixed-angle construct that stabilizes bone fragments, maintains alignment, and promotes healing under rigid fixation principles. All components are manufactured from Ti-6Al-4V ELI alloy (ASTM F136, ISO 5832-3), a biocompatible material with proven use in orthopedic implants. The system includes 2.4 mm Locking Screws, 2.7 mm Continuous Locking Screws, Spear Locking Plates, and Spear Locking Plates II. These implants are CNC-machined, surface-finished, and laser-marked, followed by validated cleaning and packaging. Supplied non-sterile and intended for single use, the devices are sterilized by healthcare providers using moist heat (ISO 17665). Mechanical testing (ASTM F382, ASTM F543) confirms that the plates and screws provide strength, stability, and fatigue resistance comparable to predicate devices, while biocompatibility has been established under the ISO 10993 series.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The APS Spear Locking Plate System is indicated for use in small bone reconstruction, corrective osteotomies, and fracture fixation.

2.4mm Locking Screw
The 2.4mm Locking Screw is intended for use with the Spear Locking Plate in metacarpal and metatarsal reconstruction, corrective osteotomies, and fracture fixation.

2.7mm Continuous Locking Screw
The 2.7mm Continuous Locking Screw is intended for use with the Spear Locking Plate, for fixation and compression at the osteotomy or fracture site. It is suitable for metacarpal and metatarsal corrective osteotomies and fracture stabilization.

Spear Locking Plate
The Spear Locking Plate is intended for use in metacarpal and metatarsal reconstruction, corrective osteotomies, and fracture fixation.

Spear Locking Plate II
The Spear Locking Plate II is intended for metacarpal and metatarsal reconstruction, corrective osteotomies, and fracture fixation.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The APS Spear Locking Plate System has the same indications for use as the predicate devices, which include reconstruction, corrective osteotomies, and fracture fixation in small bones.

Technological Comparison 21 CFR 807.92(a)(6)

The APS Spear Locking Plate System is substantially equivalent to the predicate devices, the Synthes 2.4 mm Titanium Locking Screws (K033975) and the Mini MaxLock Extreme Plating System (K101962), in terms of intended use, materials, and performance characteristics. Both systems are intended for use in small bone reconstruction, corrective osteotomies, and fracture fixation, with similar indications for use. The implants are manufactured from comparable titanium alloy materials. Mechanical testing further supports substantial equivalence. Screws were evaluated in accordance with ASTM F543, demonstrating comparable mechanical strength and insertion/removal torque to the predicate screws. Plates were evaluated in accordance with relevant test methods, including static maximum force, static bending stiffness, and bending stiffness, confirming equivalent structural integrity and mechanical performance to the predicate plating system.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Mechanical testing was conducted to support substantial equivalence of the APS Spear Locking Plate System. Bone screw testing was conducted in accordance with ASTM F543. For the plate component, testing referenced ASTM F382, but the final plate assessment used a construct-level test setup that deviated from the ASTM F382 plate-only bending configuration, because the subject device is intended to function in a first metatarsal osteotomy fixation construct rather than as an isolated plate. The construct test used first metatarsal synthetic bone models with a reproduced distal metatarsal osteotomy, with lateral-to-medial displacement-controlled static loading (5 mm/min) and plantar-to-dorsal cyclic loading from 0 to 31 N at 0.5 Hz through 1,000 cycles.

This non-standard construct setup was selected to represent clinically relevant functional loading, and interpretation of results was based on both a literature-supported physiological loading benchmark and comparison to the predicate/comparator device under identical test conditions. The results of nonclinical testing support that the APS Spear Locking Plate System is as safe and effective as the predicate device for its intended use. Clinical data were not necessary to support substantial equivalence.