December 11, 2025

A Plus Biotechnology Co., Ltd.
Helen Chan
R&D Assistant Manager
3F., No. 23, Qiaohe Rd., Zhonghe Dist.
New Taipei City, 23529
Taiwan

Re: K252897
Trade/Device Name: APS Osteotomy Fixation System (0945-1302-xx /4.5mm Cortex Screw); APS Osteotomy Fixation System (0850-4302-xx / 5.0mm Locking Screw); APS Osteotomy Fixation System (0701-xx10(1)-05 / Proximal Medial Tibial Osteotomy Locking Plate); APS Osteotomy Fixation System (0701-xx60(1)-0x / Proximal Medial Tibial Osteotomy Locking Plate, Small); APS Osteotomy Fixation System (0702-xx00(1)-03 / Proximal Lateral Tibial Osteotomy Locking Plate); APS Osteotomy Fixation System (0501-xx00(1)-04 / Distal Medial Femoral Osteotomy Locking Plate); APS Osteotomy Fixation System (0502-xx00(1)-05 / Distal Lateral Femoral Osteotomy Locking Plate)
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 11, 2025
Received: September 11, 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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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 -S

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.	K252897

Please provide the device trade name(s).

APS Osteotomy Fixation System (0945-1302-xx /4.5mm Cortex Screw);
APS Osteotomy Fixation System (0850-4302-xx / 5.0mm Locking Screw);
APS Osteotomy Fixation System (0701-xx10(1)-05 / Proximal Medial Tibial Osteotomy Locking Plate);
APS Osteotomy Fixation System (0701-xx60(1)-0x / Proximal Medial Tibial Osteotomy Locking Plate, Small);
APS Osteotomy Fixation System (0702-xx00(1)-03 / Proximal Lateral Tibial Osteotomy Locking Plate);
APS Osteotomy Fixation System (0501-xx00(1)-04 / Distal Medial Femoral Osteotomy Locking Plate);
APS Osteotomy Fixation System (0502-xx00(1)-05 / Distal Lateral Femoral Osteotomy Locking Plate)

Please provide your Indications for Use below.

4.5mm Cortex Screw
The 4.5 mm Cortical Screw is intended for use only in conjunction with compatible plates of the APS Osteotomy Fixation System. It is indicated for fixation of long bone fractures and bone fissures where high-strength cortical fixation is reguired as part of the plate-and-screw construct. The screw provides stable support at the fixation site when used as a component of the APS Osteotomy Fixation System. This screw is not intended for standalone use.

5.0mm Locking Screw
The 5.0 mm Locking Screw is intended for use only with compatible locking plates of the APS Osteotomy Fixation System. It is indicated for fixation of long bone fractures reguiring angular stability and reliable screw-plate interface fixation as part of the system construct. The locking mechanism is designed to reduce screw loosening and enhance stability at the fixation site. This screw is not intended for standalone use.

Proximal Medial Tibial Osteotomy Locking Plate
The Proximal Medial Tibial Osteotomy Locking Plate is indicated to be used in deformity correction and osteotomy procedures, providing fixation in general surgeries, reconstructive surgeries, and bone fusion or osteotomy procedures on the proximal medial tibia.

Proximal Medial Tibial Osteotomy Locking Plate, Small
The “Proximal Medial Tibial Osteotomy Locking Plate, Small” is designed for high tibial osteotomy. It is indicated for use in deformity correction and osteotomy, providing fixation in general and reconstructive surgeries, as well as bone fusion or osteotomy procedures.

Proximal Lateral Tibial Osteotomy Locking Plate
The Proximal Lateral Tibial Osteotomy Locking Plate is indicated to be used in deformity correction and osteotomy of the proximal lateral tibia, offering fixation in general surgeries, reconstructive surgeries, and bone fusion or osteotomy procedures.

Distal Medial Femoral Osteotomy Locking Plate
The Distal Medial Femoral Osteotomy Locking Plate is indicated to be used in deformity correction and osteotomy of the distal medial femur. It provides fixation in general surgeries, reconstructive surgeries, and bone fusion or osteotomy procedures.

Distal Lateral Femoral Osteotomy Locking Plate
The Distal Lateral Femoral Osteotomy Locking Plate is indicated to be used in deformity correction and osteotomy of the distal lateral femur. It provides fixation in general surgeries, reconstructive surgeries, and bone fusion or osteotomy procedures.

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) #: K252897

510(k) Summary

Prepared on: 2025-09-11

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	Ms. Helen Chan
Applicant Contact Email	aplus.helen.chen@gmail.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	APS Osteotomy Fixation System (0945-1302-xx /4.5mm Cortex Screw); APS Osteotomy Fixation System (0850-4302-xx / 5.0mm Locking Screw); APS Osteotomy Fixation System (0701-xx10(1)-05 / Proximal Medial Tibial Osteotomy Locking Plate); APS Osteotomy Fixation System (0701-xx60(1)-0x / Proximal Medial Tibial Osteotomy Locking Plate, Small); APS Osteotomy Fixation System (0702-xx00(1)-03 / Proximal Lateral Tibial Osteotomy Locking Plate); APS Osteotomy Fixation System (0501-xx00(1)-04 / Distal Medial Femoral Osteotomy Locking Plate); APS Osteotomy Fixation System (0502-xx00(1)-05 / Distal Lateral Femoral Osteotomy Locking Plate)
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
K023941	SYNTHES TOMOFIX OSTEOTOMY SYSTEM	KTT

Device Description Summary

21 CFR 807.92(a)(4)

The APS Osteotomy Fixation System is made of titanium and includes fixation plates designed for both the medial and lateral sides of the distal femur and the proximal tibia.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

4.5mm Cortex Screw

The 4.5 mm Cortical Screw is intended for use only in conjunction with compatible plates of the APS Osteotomy Fixation System. It is indicated for fixation of long bone fractures and bone fissures where high-strength cortical fixation is required as part of the plate-and-screw construct. The screw provides stable support at the fixation site when used as a component of the APS Osteotomy Fixation System. This screw is not intended for standalone use.

5.0mm Locking Screw
The 5.0mm Locking Screw is intended for use only with compatible locking plates of the APS osteotomy Fixation System. It is indicated for fixation of long bone fractures requiring angular stability and reliable screw-plate interface fixation as part of the system construct. The locking mechanism is designed to reduce screw loosening and enhance stability at the fixation site. This screw is not intended for standalone use.

Proximal Medial Tibial Osteotomy Locking Plate
The Proximal Medial Tibial osteotomy Locking Plate is indicated to be used in deformity correction and osteotomy procedures, providing fixation in general surgeries, reconstructive surgeries, and bone fusion or osteotomy procedures on the proximal medial tibia.

Proximal Medial Tibial Osteotomy Locking Plate, Small
The "Proximal Medial Tibial osteotomy Locking Plate, Small" is designed for high tibial osteotomy. It is indicated for use in deformity correction and osteotomy, providing fixation in general and reconstructive surgeries, as well as bone fusion or osteotomy procedures.

Proximal Lateral Tibial Osteotomy Locking Plate
The Proximal Lateral Tibial osteotomy Locking Plate is indicated to be used in deformity correction and osteotomy of the proximal lateral tibia, offering fixation in general surgeries, reconstructive surgeries, and bone fusion or osteotomy procedures.

Distal Medial Femoral Osteotomy Locking Plate
The Distal Medial Femoral osteotomy Locking Plate is indicated to be used in deformity correction and osteotomy of the distal medial femur. It provides fixation in general surgeries, reconstructive surgeries, and bone fusion or osteotomy procedures.

Distal Lateral Femoral Osteotomy Locking Plate
The Distal Lateral Femoral osteotomy Locking Plate is indicated to be used in deformity correction and osteotomy of the distal lateral femur. It provides fixation in general surgeries, reconstructive surgeries, and bone fusion or osteotomy procedures.

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

The APS Osteotomy Fixation System is indicated for fixation of bone segments to correct deformities of the knee joint in the distal femur or proximal tibia. This is similar to the Synthes TomoFix™ Osteotomy System, which is intended for osteotomies of the proximal tibia and distal femur to treat deformities and malalignment. Both devices are intended for fixation during osteotomy procedures to correct deformities around the knee joint in the same anatomical regions.

Technological Comparison 21 CFR 807.92(a)(6)

The APS Osteotomy Fixation System is substantially equivalent to the predicate device, the Synthes TomoFix™ Osteotomy System, in terms of intended use, materials, and performance characteristics.Both systems are intended for the fixation of bone segments to correct deformities of the distal femur or proximal tibia, with identical indications for use.The implants are manufactured from comparable titanium alloy materials. Mechanical testing confirms equivalent performance between the two systems:Screws were evaluated in accordance with ASTM F543, demonstrating comparable strength and insertion/removal torque. Plates were tested per ASTM F382, exhibiting similar bending stiffness and structural integrity.

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

Mechanical testing was conducted in accordance with ASTM F382 for bone plates and ASTM F543 for bone screws. Results were comparable to those of the predicate device and support substantial equivalence.

Not Applicable.
Clinical data were not necessary to support substantial equivalence of the APS Osteotomy Fixation System. The determination was based on nonclinical mechanical testing conducted in accordance with FDA-recognized standards and comparison to the predicate device.

The results of the nonclinical mechanical testing, conducted per ASTM F382 and ASTM F543, demonstrate that the APS Osteotomy Fixation System is as safe, as effective, and performs as well as the predicate device.