

K252897 APS Osteotomy Fixation System (0945-1302-xx /4.5mm Cortex Screw)

Dec 11, 2025
91 days to decision

K252897 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k252897/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Sep 11, 2025
Decision date	Dec 11, 2025
Days to decision	91 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	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 / Dista

APPLICANT

Company	A Plus Biotechnology Co., Ltd.
Location	New Taipei City, TW
Contact	Helen Chan
510(k) history	3 submissions · 3 cleared · 2023-2026

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Device record: <https://www.510kdatabase.net/k252897/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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