

K254053 APS Spear Locking PlateMar 17, 2026
90 days to decisionK254053 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k254053/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Dec 17, 2025
Decision date	Mar 17, 2026
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k254053/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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