

K254288 Clavicle Fixation SystemMar 23, 2026
82 days to decisionK254288 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k254288/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Plate, Fixation, Bone (HRS)
Date received	Dec 31, 2025
Decision date	Mar 23, 2026
Days to decision	82 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Skeletal Dynamics, Inc.
Location	Miami, FL, US
Contact	Alexandra Rodriguez Rojas
510(k) history	20 submissions · 20 cleared · 2020-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k254288/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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