

K240181 Clavicle and Scapula SystemOct 9, 2024
260 days to decisionK240181 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k240181/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Jan 23, 2024
Decision date	Oct 9, 2024
Days to decision	260 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Auxein Medical Pvt., Ltd.
Location	Sonepat, IN
Contact	Gaurav Luthra
510(k) history	1 submissions · 1 cleared · 2024-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k240181/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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