

K213108 Humerus & Ulna SystemNov 4, 2022
406 days to decisionK213108 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k213108/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Sep 24, 2021
Decision date	Nov 4, 2022
Days to decision	406 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Auxein Medical Private Limited
Location	Sonipat, IN
Contact	Rahul Luthra
510(k) history	12 submissions · 12 cleared · 2020-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213108/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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