

K210792 Auxein Nailing SystemAug 25, 2021
163 days to decisionK210792 · Product code: **HWC** · Orthopedic
Source: <https://www.510kdatabase.net/k210792/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Screw, Fixation, Bone (HWC)
Date received	Mar 15, 2021
Decision date	Aug 25, 2021
Days to decision	163 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/k210792/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026