

K221787 Auxein's DHS/DCS Plate SystemNov 30, 2023
527 days to decisionK221787 · Product code: **KTT** · Orthopedic
Source: <https://www.510kdatabase.net/k221787/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Nail/blade/plate Combination, Multiple Component (KTT)
Date received	Jun 21, 2022
Decision date	Nov 30, 2023
Days to decision	527 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/k221787/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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