

**K213059 Tibia and Fibula System**Jan 27, 2023  
492 days to decisionK213059 · Product code: **HRS** · Orthopedic  
Source: <https://www.510kdatabase.net/k213059/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Sep 22, 2021
Decision date	Jan 27, 2023
Days to decision	492 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k213059/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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