

K211261 Axis Charcot Fixation SystemMay 28, 2021
32 days to decisionK211261 · Product code: **HWC** · Orthopedic
Source: <https://www.510kdatabase.net/k211261/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Screw, Fixation, Bone (HWC)
Date received	Apr 26, 2021
Decision date	May 28, 2021
Days to decision	32 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Extremity Medical, LLC
Location	Parsippany, NJ, US
Contact	Mary Hoffman
510(k) history	28 submissions · 28 cleared · 2008-2025

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