

K181067 AlignX Ankle Fusion SystemMay 23, 2018
30 days to decisionK181067 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k181067/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Plate, Fixation, Bone (HRS)
Date received	Apr 23, 2018
Decision date	May 23, 2018
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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