

K212640 Stratum® Ankle Fusion Plating SystemNov 18, 2021
90 days to decisionK212640 · Product code: **HRS** · General Hospital
Source: <https://www.510kdatabase.net/k212640/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Aug 20, 2021
Decision date	Nov 18, 2021
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Nextremity Solutions, Inc.
Location	Red Bank, NJ, US
Contact	Elise Fox
510(k) history	17 submissions · 17 cleared · 2014-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212640/> 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