

K213301 InCore Subtalar SystemDec 21, 2021
81 days to decisionK213301 · Product code: **HWC** · Orthopedic
Source: <https://www.510kdatabase.net/k213301/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Oct 1, 2021
Decision date	Dec 21, 2021
Days to decision	81 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

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