

K192578 InCore TMT SystemDec 31, 2019
103 days to decisionK192578 · Product code: **HWC** · Orthopedic
Source: <https://www.510kdatabase.net/k192578/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Sep 19, 2019
Decision date	Dec 31, 2019
Days to decision	103 days
Third-party review	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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