

K183236 Rotium Bioresorbable WickMar 11, 2019
111 days to decisionK183236 · Product code: **MAI** · Orthopedic
Source: <https://www.510kdatabase.net/k183236/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Biodegradable, Soft Tissue (MAI)
Date received	Nov 20, 2018
Decision date	Mar 11, 2019
Days to decision	111 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Nanofiber Solutions, LLC
Location	Hilliard, OH, US
Contact	Ronald L. Bracken
510(k) history	5 submissions · 5 cleared · 2019-2025

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