

K201414 Rotium Bioresorbable WickJun 25, 2020
27 days to decisionK201414 · Product code: **MAI** · Orthopedic
Source: <https://www.510kdatabase.net/k201414/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Fastener, Fixation, Biodegradable, Soft Tissue (MAI)
Date received	May 29, 2020
Decision date	Jun 25, 2020
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Nanofiber Solutions, LLC
Location	Hilliard, OH, US
Contact	Jason Chakroff
510(k) history	5 submissions · 5 cleared · 2019-2025

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