FDA 510(k) Premarket Notification

K203121 Responsive Arthroscopy Thunderbolt System

CLEARED

Apr 27, 2021
193 days to decision

K203121 · Product code: **MBI** · Orthopedic
Source: https://www.510kdatabase.net/k203121/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Oct 16, 2020
Decision date	Apr 27, 2021
Days to decision	193 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Responsive Arthroscopy, LLC**
Location	Minneapolis, MN, US
Contact	Douglas Kohrs
510(k) history	11 submissions · 11 cleared · 2018-2025

REGULATORY CONSULTANT

Consulting firm	**Cor Medical Ventures, Inc.**
Contact	Benjamin Arnold

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov