FDA 510(k) Premarket Notification

K243988 RootMend MRR

CLEARED

Mar 20, 2025
84 days to decision

K243988 · Product code: **MBI** · Orthopedic
Source: https://www.510kdatabase.net/k243988/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Dec 26, 2024
Decision date	Mar 20, 2025
Days to decision	84 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Riverpoint Medical, LLC**
Location	Portland, OR, US
Contact	Jacquelyn Pinnel
510(k) history	11 submissions · 11 cleared · 2020-2026