FDA 510(k) Premarket Notification

K233030 BoneMRI

CLEARED

Mar 1, 2024
158 days to decision

K233030 · Product code: **QIH** · Radiology
Source: https://www.510kdatabase.net/k233030/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Sep 25, 2023
Decision date	Mar 1, 2024
Days to decision	158 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary

APPLICANT

Company	**Mriguidance B.V.**
Location	Utrecht, NL
Contact	David Sparks
510(k) history	3 submissions · 3 cleared · 2021-2024

REGULATORY CONSULTANT

Consulting firm	**Maxis Medical**
Contact	Sujith Shetty

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