FDA 510(k) Premarket Notification

K221762 BoneMRI v1.4

CLEARED

Nov 16, 2022
152 days to decision

K221762 · Product code: **QIH** · Radiology
Source: https://www.510kdatabase.net/k221762/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Jun 17, 2022
Decision date	Nov 16, 2022
Days to decision	152 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Mrlguidance B.V.**
Location	Utrecht, NL
Contact	Marijn van Stralen
510(k) history	1 submissions · 1 cleared · 2022-2022

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