FDA 510(k) Premarket Notification

K202404 BoneMRI

CLEARED

Dec 22, 2021
488 days to decision

K202404 · Product code: **QIH** · Radiology
Source: https://www.510kdatabase.net/k202404/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Aug 21, 2020
Decision date	Dec 22, 2021
Days to decision	488 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	**Maxis Medical**
Contact	Suji Shetty

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