

K202404 BoneMRIDec 22, 2021
488 days to decisionK202404 · 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.gov510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k202404/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026