FDA 510(k) Premarket Notification

K220758 e-Ortho Shoulder Software v1.1

CLEARED

Sep 30, 2022
199 days to decision

K220758 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k220758/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Mar 15, 2022
Decision date	Sep 30, 2022
Days to decision	199 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**FH Industrie**
Location	Quimper Finistere, FR
Contact	Oscar Ramirez
510(k) history	9 submissions · 9 cleared · 2020-2026

REGULATORY CONSULTANT

Consulting firm	**MRC Global, LLC**
Contact	Dawn N. Norman

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