FDA 510(k) Premarket Notification

K240172 Preview Shoulder

CLEARED

Apr 4, 2024
73 days to decision

K240172 · Product code: **QIH** · Radiology
Source: https://www.510kdatabase.net/k240172/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Jan 22, 2024
Decision date	Apr 4, 2024
Days to decision	73 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Genesis Software Innovations**
Location	Grand Rapids, MI, US
Contact	Matt Miller
510(k) history	2 submissions · 2 cleared · 2021-2024