

K213272 Formus HipMar 31, 2023
547 days to decisionK213272 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k213272/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Sep 30, 2021
Decision date	Mar 31, 2023
Days to decision	547 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Formus Labs, Ltd.
Location	Auckland, NZ
Contact	Richie Christian
510(k) history	1 submissions · 1 cleared · 2023-2023

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