

K252249 Extremity CT Imaging SystemMar 13, 2026
238 days to decisionK252249 · Product code: **JAK** · Radiology
Source: <https://www.510kdatabase.net/k252249/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Jul 18, 2025
Decision date	Mar 13, 2026
Days to decision	238 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Mars Bioimaging , Ltd.
Location	Christchurch, NZ
Contact	Homi Dalal
Website	https://marsbioimaging.com
510(k) history	1 submissions · 1 cleared · 2026-2026

Mars Bioimaging, Ltd. is a medical device company pioneering photon counting CT imaging technology. Based in Christchurch, New Zealand, the company develops advanced diagnostic imaging systems designed for point-of-care use. Their flagship system delivers high-resolution extremity imaging with spectral material detection and reduced radiation exposure. The company has received FDA 510(k) clearance from total submission. Mars Bioimaging specializes in Radiology devices, with its cleared Extremity CT Imaging System representing the company's core regulatory focus. The compa...

REGULATORY CONSULTANT

Consulting firm	MEDIcept
Contact	Melissa DeHass

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

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Device record: <https://www.510kdatabase.net/k252249/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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