

K250288 TeraRecon Cardiovascular.Calcification.CTOct 23, 2025
265 days to decisionK250288 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k250288/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Jan 31, 2025
Decision date	Oct 23, 2025
Days to decision	265 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Terarecon, Inc.
Location	Pleasant Hill, CA, US
Contact	Alexis Ferrier
510(k) history	14 submissions · 14 cleared · 1998-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250288/> 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 14, 2026