

K083649 CARDIUS 3 X-ACTMar 9, 2009
90 days to decisionK083649 · Product code: **KPS** · Radiology
Source: <https://www.510kdatabase.net/k083649/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Tomography, Computed, Emission (KPS)
Date received	Dec 9, 2008
Decision date	Mar 9, 2009
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Digirad Corp.
Location	Palo Alto, CA, US
Contact	Joel Tuckey
510(k) history	16 submissions · 16 cleared · 1983-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k083649/> 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 17, 2026