FDA 510(k) Premarket Notification

K083649 CARDIUS 3 X-ACT

CLEARED

Mar 9, 2009
90 days to decision

K083649 · 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