FDA 510(k) Premarket Notification

K082368 CARDIUS-1, -2, -3, AND CARDIUS 1,2,3 XPO SPECT IMAGING SYSTEMS, 2020TC SPECT IMAGING SYSTEM

CLEARED

Sep 12, 2008
25 days to decision

K082368 · Product code: **KPS** · Radiology
Source: https://www.510kdatabase.net/k082368/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Tomography, Computed, Emission (KPS)
Date received	Aug 18, 2008
Decision date	Sep 12, 2008
Days to decision	25 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