

K131314 DDRCRUZE (DIGITAL MOBILE DIAGNOSTIC X-RAY SYSTEM)Jun 25, 2013
49 days to decisionK131314 · Product code: **MQB** · Radiology
Source: <https://www.510kdatabase.net/k131314/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Solid State X-ray Imager (flat Panel/digital Imager) (MQB)
Date received	May 7, 2013
Decision date	Jun 25, 2013
Days to decision	49 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Swissray Medical AG
Location	Elizabeth, NJ, US
Contact	TODD SHOPP
510(k) history	4 submissions · 4 cleared · 2005-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k131314/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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