

K102529 D2RF DIGITAL DYNAMIC REMOTE SYSTEM

Oct 7, 2010
35 days to decision

K102529 · Product code: **OWB** · Radiology
Source: <https://www.510kdatabase.net/k102529/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Sep 2, 2010
Decision date	Oct 7, 2010
Days to decision	35 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Stephanix Radiological Systems
Location	Naples, FL, US
Contact	DANIEL KAMM
510(k) history	1 submissions · 1 cleared · 2010-2010

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k102529/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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