FDA 510(k) Premarket Notification

K212523 VFSS Pro Mobile Digital Imaging System

CLEARED

Nov 5, 2021
86 days to decision

K212523 · Product code: **OWB** · Radiology
Source: https://www.510kdatabase.net/k212523/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Aug 11, 2021
Decision date	Nov 5, 2021
Days to decision	86 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Imagexray, LLC**
Location	Nutley, NJ, US
Contact	Gary Korkola
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	**Kamm & Associates**
Contact	Daniel Kamm

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov