

K212557 Virtual C DRF-NEO Digital Imaging SystemSep 24, 2021
42 days to decisionK212557 · Product code: **OWB** · Radiology
Source: <https://www.510kdatabase.net/k212557/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Aug 13, 2021
Decision date	Sep 24, 2021
Days to decision	42 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Portavision Medical, LLC
Location	Kenner, LA, US
Contact	Terry Ancar
510(k) history	5 submissions · 5 cleared · 2008-2021

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.gov510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212557/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026