FDA 510(k) Premarket Notification

K243303 Ziehm Vision RFD 3D

CLEARED

Jan 21, 2025
92 days to decision

K243303 · Product code: **OWB** · Radiology
Source: https://www.510kdatabase.net/k243303/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Oct 21, 2024
Decision date	Jan 21, 2025
Days to decision	92 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Ziehm Imaging GmbH**
Location	Orlando, FL, US
Contact	Tsvetelina Milanova
510(k) history	18 submissions · 18 cleared · 2013-2025