FDA 510(k) Premarket Notification

K233380 TRIDENT Mobile Fluoroscopy System

CLEARED

Jun 26, 2024
268 days to decision

K233380 · Product code: **JAA** · Radiology
Source: https://www.510kdatabase.net/k233380/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Fluoroscopic, Image-intensified (JAA)
Date received	Oct 2, 2023
Decision date	Jun 26, 2024
Days to decision	268 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Dornier Medtech America**
Location	Kennesaw, GA, US
Contact	John Hoffer
510(k) history	6 submissions · 6 cleared · 2013-2025