FDA 510(k) Premarket Notification

CLEARED

K082243 PRECISION RXI ANALOG AND DIGITAL X-RAY SYSTEMS

Nov 7, 2008
92 days to decision

K082243 · Product code: **OWB** · Radiology
Source: https://www.510kdatabase.net/k082243/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Aug 7, 2008
Decision date	Nov 7, 2008
Days to decision	92 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**General Medical Merate S.P.A**
Location	Seriate, Bergamo, IT
Contact	Kevin Walls
510(k) history	7 submissions · 7 cleared · 1982-2021