

K082243 PRECISION RXI ANALOG AND DIGITAL X-RAY SYSTEMSNov 7, 2008
92 days to decisionK082243 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k082243/> 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