

K063283 DEFINIUM 5000 X-RAY SYSTEMNov 17, 2006
18 days to decisionK063283 · Product code: **MQB** · Radiology
Source: <https://www.510kdatabase.net/k063283/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Solid State X-ray Imager (flat Panel/digital Imager) (MQB)
Date received	Oct 30, 2006
Decision date	Nov 17, 2006
Days to decision	18 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sedecal., Sa.
Location	Deer Field, IL, US
Contact	DANIEL KAMM
510(k) history	26 submissions · 26 cleared · 2002-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k063283/> 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 18, 2026