

K963395 IMAGESERVER 2000 PICTURE ARCHIVING SYSTEMOct 25, 1996
58 days to decisionK963395 · Product code: **LMB** · Radiology
Source: <https://www.510kdatabase.net/k963395/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Digital Image Storage, Radiological (LMB)
Date received	Aug 28, 1996
Decision date	Oct 25, 1996
Days to decision	58 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sectra-Imtec AB
Location	Aubrey, TX, US
Contact	HERMAN OOSTERWIJK
510(k) history	14 submissions · 14 cleared · 1996-2011

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k963395/> 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 17, 2026