

K944196 IMWXDOP IRMay 12, 1995
256 days to decisionK944196 · Product code: **JAF** · Radiology
Source: <https://www.510kdatabase.net/k944196/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Ultrasonic, Nonfetal (JAF)
Date received	Aug 29, 1994
Decision date	May 12, 1995
Days to decision	256 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Imex Medical Systems, Inc.
Location	Mchenry, IL, US
Contact	DENNIS NEWMAN
510(k) history	19 submissions · 19 cleared · 1983-1998

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k944196/> 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 19, 2026