

K031281 ERGO SRSDec 23, 2003
245 days to decisionK031281 · Product code: **MUJ** · Radiology
Source: <https://www.510kdatabase.net/k031281/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Planning, Radiation Therapy Treatment (MUJ)
Date received	Apr 22, 2003
Decision date	Dec 23, 2003
Days to decision	245 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	3D Line USA, Inc.
Location	Baltimore, MD, US
Contact	NADER SALEHI
510(k) history	6 submissions · 6 cleared · 2000-2004

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k031281/> 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