FDA 510(k) Premarket Notification

K031281 ERGO SRS

CLEARED

Dec 23, 2003
245 days to decision

K031281 · 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