FDA 510(k) Premarket Notification

K012290 RAPIDIA

CLEARED

Sep 28, 2001
70 days to decision

K012290 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k012290/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jul 20, 2001
Decision date	Sep 28, 2001
Days to decision	70 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**3D Med Co., Ltd.**
Location	North Attleboro, MA, US
Contact	CYNTHIA J.M. NOLTE
510(k) history	2 submissions · 2 cleared · 2001-2002