FDA 510(k) Premarket Notification

K030457 REX, VERSION 3.0

CLEARED

Apr 8, 2003
56 days to decision

K030457 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k030457/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Feb 11, 2003
Decision date	Apr 8, 2003
Days to decision	56 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Pointdx, Inc.**
Location	Winston-Salem, NC, US
Contact	FRANCIS BONK
510(k) history	2 submissions · 2 cleared · 2002-2003