FDA 510(k) Premarket Notification

K014022 MRI LINE MARKER

CLEARED

Mar 4, 2002
88 days to decision

K014022 · Product code: **IYE** · Radiology
Source: https://www.510kdatabase.net/k014022/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Dec 6, 2001
Decision date	Mar 4, 2002
Days to decision	88 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**I.Z.I. Corp.**
Location	Owings Mills, MD, US
Contact	HELEN ZINREICH
510(k) history	7 submissions · 7 cleared · 1992-2002