FDA 510(k) Premarket Notification

K023449 NON-INVASIVE PATIENT FIXATION SYSTEM

CLEARED

Jan 13, 2003
90 days to decision

K023449 · Product code: **IYE** · Radiology
Source: https://www.510kdatabase.net/k023449/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Oct 15, 2002
Decision date	Jan 13, 2003
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Stryker Leibinger**
Location	Kalamazoo, MI, US
Contact	KELLI J BITTERBURG
510(k) history	12 submissions · 12 cleared · 1999-2005