FDA 510(k) Premarket Notification

K013595 PREMIER III PHASED ARRAY CTL SPINE COIL

CLEARED

Jan 22, 2002
84 days to decision

K013595 · Product code: **MOS** · Radiology
Source: https://www.510kdatabase.net/k013595/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Coil, Magnetic Resonance, Specialty (MOS)
Date received	Oct 30, 2001
Decision date	Jan 22, 2002
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Usa Instruments, Inc.**
Location	Aurora, OH, US
Contact	RONY THOMAS
510(k) history	64 submissions · 64 cleared · 1997-2005