FDA 510(k) Premarket Notification

K031366 PREMIER 9000 8 CHANNEL PHASED ARRAY CTL SPINE COIL

CLEARED

Jul 11, 2003
72 days to decision

K031366 · Product code: **MOS** · Radiology
Source: https://www.510kdatabase.net/k031366/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Coil, Magnetic Resonance, Specialty (MOS)
Date received	Apr 30, 2003
Decision date	Jul 11, 2003
Days to decision	72 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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