FDA 510(k) Premarket Notification

CLEARED

K031056 MODIFICATION TO PREMIER III PHASED ARRAY CTL SPINE COIL

May 8, 2003
35 days to decision

K031056 · Product code: **MOS** · Radiology
Source: https://www.510kdatabase.net/k031056/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Coil, Magnetic Resonance, Specialty (MOS)
Date received	Apr 3, 2003
Decision date	May 8, 2003
Days to decision	35 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