FDA 510(k) Premarket Notification

K980157 PREMIER 7000 CTL SPINE COIL

CLEARED

Apr 13, 1998
87 days to decision

K980157 · Product code: **MOS** · Radiology
Source: https://www.510kdatabase.net/k980157/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Coil, Magnetic Resonance, Specialty (MOS)
Date received	Jan 16, 1998
Decision date	Apr 13, 1998
Days to decision	87 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