FDA 510(k) Premarket Notification

K031731 MR FIBER OPTIC ECG GATING SYSTEM

CLEARED

Jul 30, 2003
56 days to decision

K031731 · Product code: **LNH** · Radiology
Source: https://www.510kdatabase.net/k031731/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Jun 4, 2003
Decision date	Jul 30, 2003
Days to decision	56 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Sa Instruments, Inc.**
Location	Stony Brook, NY, US
Contact	G. RONALD MORRIS
510(k) history	1 submissions · 1 cleared · 2003-2003