FDA 510(k) Premarket Notification

K992533 PHILIPS GYROSCAN INTERA (*)

CLEARED

Oct 18, 1999
81 days to decision

K992533 · Product code: **LNH** · Radiology
Source: https://www.510kdatabase.net/k992533/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Jul 29, 1999
Decision date	Oct 18, 1999
Days to decision	81 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Philips Medical Systems North America, Inc.**
Location	Shelton, CT, US
Contact	PETER ALTMAN
510(k) history	71 submissions · 71 cleared · 1989-2010