FDA 510(k) Premarket Notification

K001796 GYROSCAN INTERA (R7.5)

CLEARED

Sep 6, 2000
84 days to decision

K001796 · Product code: **LNH** · Radiology
Source: https://www.510kdatabase.net/k001796/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Jun 14, 2000
Decision date	Sep 6, 2000
Days to decision	84 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