FDA 510(k) Premarket Notification

K896419 MODEL: GYREX VERSION V

CLEARED

Feb 2, 1990
86 days to decision

K896419 · Product code: **LNH** · Radiology
Source: https://www.510kdatabase.net/k896419/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Nov 8, 1989
Decision date	Feb 2, 1990
Days to decision	86 days
Third-party review	No

APPLICANT

Company	**Elscint, Inc.**
Location	Mchenry, IL, US
Contact	STEVE BEER
510(k) history	94 submissions · 94 cleared · 1981-1998