FDA 510(k) Premarket Notification

K884644 ADDIT. TRANS. EUP-B31/033J/V33/U33/032T/L33/U322

CLEARED

Apr 13, 1990
522 days to decision

K884644 · Product code: **IYO** · Radiology
Source: https://www.510kdatabase.net/k884644/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Nov 7, 1988
Decision date	Apr 13, 1990
Days to decision	522 days
Third-party review	No

APPLICANT

Company	**Hitachi Medical Corp. of America**
Location	Tarrytown, NY, US
Contact	TAKIGUCHI
510(k) history	32 submissions · 31 cleared · 1985-2000