FDA 510(k) Premarket Notification

K800099 INTRACULA II

CLEARED

Feb 21, 1980
38 days to decision

K800099 · Product code: **IYO** · Radiology
Source: https://www.510kdatabase.net/k800099/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Jan 14, 1980
Decision date	Feb 21, 1980
Days to decision	38 days
Third-party review	No

APPLICANT

Company	**Kt Medical, Inc.**
Location	Mchenry, IL, US
510(k) history	13 submissions · 13 cleared · 1980-1980