FDA 510(k) Premarket Notification

K883238 GENESIS II TRANSCRANIAL PROBE

CLEARED

Aug 24, 1988
23 days to decision

K883238 · Product code: **IYO** · Radiology
Source: https://www.510kdatabase.net/k883238/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Aug 1, 1988
Decision date	Aug 24, 1988
Days to decision	23 days
Third-party review	No

APPLICANT

Company	**Biosound, Inc.**
Location	Indianapolis, IN, US
Contact	ROBERT COURTNEY
510(k) history	39 submissions · 39 cleared · 1983-1997