FDA 510(k) Premarket Notification

K895645 BIOSOUND PHASE 2 DIAGNOSTIC ULTRASOUND SYSTEM

CLEARED

Mar 6, 1990
167 days to decision

K895645 · Product code: **IYO** · Radiology
Source: https://www.510kdatabase.net/k895645/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Sep 20, 1989
Decision date	Mar 6, 1990
Days to decision	167 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k895645/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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