

K896356 AU530 DIAGNOSTIC ULTRASONIC PULSED ECHO SYSTEMAug 21, 1990
288 days to decisionK896356 · Product code: **IYO** · Radiology
Source: <https://www.510kdatabase.net/k896356/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Nov 6, 1989
Decision date	Aug 21, 1990
Days to decision	288 days
Third-party review	No

APPLICANT

Company	Esaote Biomedica Spa
Location	Cambridge, MA, US
Contact	SAYIGH, PHD
510(k) history	4 submissions · 4 cleared · 1990-1994

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k896356/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 21, 2026