

K963863 JANUS IApr 21, 1997
207 days to decisionK963863 · Product code: **IYO** · Radiology
Source: <https://www.510kdatabase.net/k963863/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Sep 26, 1996
Decision date	Apr 21, 1997
Days to decision	207 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	3D Ultrasound, Inc.
Location	Durham, NC, US
Contact	JOHN OXAAL
510(k) history	2 submissions · 2 cleared · 1995-1997

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