

**K963315 VINGMED SOUND COLOR FLOW MAPPING SYSTEM.
SYSTEM FIVE**

Mar 17, 1997
207 days to decision

K963315 · Product code: **IYO** · Radiology
Source: <https://www.510kdatabase.net/k963315/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Aug 22, 1996
Decision date	Mar 17, 1997
Days to decision	207 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Vingmed Sound, Inc.
Location	Horten, NO
Contact	WALTER E GUNDAKER
510(k) history	3 submissions · 3 cleared · 1993-1997

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Device record: <https://www.510kdatabase.net/k963315/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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