

K980468 AU5 ULTRASOUND IMAGING SYSTEMAug 26, 1998
201 days to decisionK980468 · Product code: IYN · Radiology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Feb 6, 1998
Decision date	Aug 26, 1998
Days to decision	201 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biosound Esaote, Inc.
Location	Indianapolis, IN, US
Contact	COLLEEN HITTLE
510(k) history	20 submissions · 20 cleared · 1997-2003

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