

K053084 SIGMA 5000 SERIES IMAGIC ULTRASOUND SYSTEMNov 16, 2005
14 days to decisionK053084 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k053084/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Nov 2, 2005
Decision date	Nov 16, 2005
Days to decision	14 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Kontron Medical Systems Sas
Location	Hasbrouck Heights, NJ, US
Contact	LARRY WALKER
510(k) history	4 submissions · 4 cleared · 2000-2006

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