FDA 510(k) Premarket Notification

K091970 AIXPLORER ULTRASOUND SYSTEM

CLEARED

Aug 12, 2009
42 days to decision

K091970 · Product code: **IYN** · Radiology
Source: https://www.510kdatabase.net/k091970/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Jul 1, 2009
Decision date	Aug 12, 2009
Days to decision	42 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Supersonic Imagine**
Location	Aix-En-Provence Cedex, FR
Contact	JACQUES SOUQUET
510(k) history	16 submissions · 16 cleared · 2009-2024

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k091970/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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