

**K180572 AIXPLORER MACH Ultrasound Diagnostic Systems
Aixplorer Mach 30, Aixplorer Mach 20, Aixplorer Mach 10**May 29, 2018
85 days to decisionK180572 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k180572/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Mar 5, 2018
Decision date	May 29, 2018
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k180572/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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