

K202455 Aixplorer®MACH20, Aixplorer®MACH30, Supersonic MACH40, Supersonic MACH30 & Supersonic MACH20 Ultrasonic Diagnostic SystemsDec 29, 2020
124 days to decisionK202455 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k202455/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Aug 27, 2020
Decision date	Dec 29, 2020
Days to decision	124 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.netDevice record: <https://www.510kdatabase.net/k202455/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026