

K191007 Aixplorer MACH 30, Aixplorer MACH 20 Ultrasound Diagnostic SystemsOct 25, 2019
192 days to decisionK191007 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k191007/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Imaging, Pulsed Doppler, Ultrasonic (IYN) |
| Date received | Apr 16, 2019 |
| Decision date | Oct 25, 2019 |
| Days to decision | 192 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 |

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