

K202742 Dolphin/IQ, Dolphin/4D and Dolphin/MAX with Dolphin/XF robot accessoryJan 25, 2021
129 days to decisionK202742 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k202742/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Sep 18, 2020
Decision date	Jan 25, 2021
Days to decision	129 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Viasonix , Ltd.
Location	Yonkers, NY, US
Contact	Dan Manor
510(k) history	6 submissions · 6 cleared · 2011-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k202742/> 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