

K220983 ImSonic TR-1 Ultrasonic Pulsed Doppler Imaging SystemNov 11, 2022
221 days to decisionK220983 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k220983/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Apr 4, 2022
Decision date	Nov 11, 2022
Days to decision	221 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Imsonic Medical China, Inc.
Location	Kunshan, CN
Contact	Xiaohui Hao
510(k) history	1 submissions · 1 cleared · 2022-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k220983/> 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