

K211248 ArtUsFeb 11, 2022
291 days to decisionK211248 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k211248/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Apr 26, 2021
Decision date	Feb 11, 2022
Days to decision	291 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Teleded
Location	Vilnius, LT
Contact	Yury Sokolov
510(k) history	5 submissions · 5 cleared · 2011-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211248/> 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 27, 2026