

K162155 Xario 200 Diagnostic Ultrasound System V5.0Nov 1, 2016
91 days to decisionK162155 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k162155/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Aug 2, 2016
Decision date	Nov 1, 2016
Days to decision	91 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Toshibamedical Systems Corporation
Location	Tustin, CA, US
Contact	PAUL BIGGINS
510(k) history	80 submissions · 80 cleared · 2004-2018

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k162155/> 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 16, 2026