

K182628 Imagio Ultrasound Imaging SystemMar 5, 2019
162 days to decisionK182628 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k182628/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Sep 24, 2018
Decision date	Mar 5, 2019
Days to decision	162 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Seno Medical Instruments, Inc.
Location	San Antonio, TX, US
Contact	Katherin Harris
510(k) history	1 submissions · 1 cleared · 2019-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k182628/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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