

K192388 SonoVision Ultrasound Imaging SystemMar 12, 2020
191 days to decisionK192388 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k192388/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Sep 3, 2019
Decision date	Mar 12, 2020
Days to decision	191 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Tissue Differentiation Intelligence, LLC
Location	Delray Beach, FL, US
Contact	Christian Zaal
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Qserve Group, Us, Inc.
Contact	Lorry Weaver Huffman

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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