FDA 510(k) Premarket Notification

K192254 InnoSight Diagnostic Ultrasound System

CLEARED

Sep 18, 2019
29 days to decision

K192254 · Product code: **IYN** · Radiology
Source: https://www.510kdatabase.net/k192254/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Aug 20, 2019
Decision date	Sep 18, 2019
Days to decision	29 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Qisda Corporation**
Location	Dublin, CA, US
Contact	Johnson Sheu
510(k) history	4 submissions · 4 cleared · 2014-2019

REGULATORY CONSULTANT

Consulting firm	**Regulatory Technology Services, LLC**
Contact	Prithul Bom

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