FDA 510(k) Premarket Notification

K191922 ACUSON P200 Diagnostic Ultrasound System

CLEARED

Aug 15, 2019
28 days to decision

K191922 · Product code: **IYN** · Radiology
Source: https://www.510kdatabase.net/k191922/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Jul 18, 2019
Decision date	Aug 15, 2019
Days to decision	28 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Siemens Medical Solutions USA, Inc.**
Location	Hoffman Estates, IL, US
Contact	HyunJung Lee
510(k) history	779 submissions · 779 cleared · 1980-2026

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