

K202683 ACUSON Sequoia Diagnostic Ultrasound System, ACUSON SC2000 Diagnostic Ultrasound System, ACUSON Freestyle Diagnostic Ultrasound System, ACUSON S1000, S2000, S3000 Diagnostic Ultrasound Systems, ACUSON P200 Diagnostic Ultrasound System, ACUSON P500 Diagnostic Ultrasound System, ACUSON NX3, NX3 Elite Diagnostic Ultrasound System

Oct 15, 2020
30 days to decision

K202683 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k202683/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Sep 15, 2020
Decision date	Oct 15, 2020
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k202683/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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