

K231509 Aco Apache Ultrasound SystemOct 24, 2023
152 days to decisionK231509 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k231509/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	May 25, 2023
Decision date	Oct 24, 2023
Days to decision	152 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Aco Healthcare Co., Ltd.
Location	Hsinchu, TW
Contact	Henry Huang
510(k) history	2 submissions · 2 cleared · 2021-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231509/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026