

K211232 Apache Ultrasound SystemJun 25, 2021
63 days to decisionK211232 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k211232/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Apr 23, 2021
Decision date	Jun 25, 2021
Days to decision	63 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/k211232/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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