

**K202074 Apache Ultrasound System (Model C62)**Nov 12, 2020  
108 days to decisionK202074 · Product code: **IYN** · Radiology  
Source: <https://www.510kdatabase.net/k202074/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Jul 27, 2020
Decision date	Nov 12, 2020
Days to decision	108 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Compal Electronics, Inc.</b>
Location	Taipei, TW
Contact	DK Lee
Website	<a href="http://www.compal.com">http://www.compal.com</a>
510(k) history	3 submissions · 3 cleared · 2020-2026

Compal Electronics, Inc. is a leading global manufacturer of advanced electronics and computing devices, with a manufacturing facility in Taipei, Taiwan. The company specializes in notebook PCs, LCD products, smart devices, and healthcare technology solutions, serving Fortune 500 companies and emerging startups worldwide. Compal has received FDA 510(k) clearances from total submissions since its first clearance in 2020. The company's cleared devices span multiple medical specialties, including anesthesiology, general and plastic surgery, and radiology. The latest clearanc...

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