

**K212400 SONON Ultrasound Imaging System, Model: SONON 500L**Apr 22, 2022  
263 days to decisionK212400 · Product code: IYN · Radiology  
Source: <https://www.510kdatabase.net/k212400/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Aug 2, 2021
Decision date	Apr 22, 2022
Days to decision	263 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Healcerion Co., Ltd.</b>
Location	Seoul, KR
Contact	Sooyeol Lee
510(k) history	4 submissions · 4 cleared · 2015-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Gms Consulting</b>
Contact	Jong Hyun Kim

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212400/>. Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 27, 2026