

**K211665 SONON Ultrasound Imaging System, Model:
SONON300C**May 16, 2022
349 days to decisionK211665 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k211665/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Jun 1, 2021
Decision date	May 16, 2022
Days to decision	349 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Gms Consulting Co., Ltd.
Contact	Jong Hyun Kim

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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