

K170085 SONON Ultrasound Imaging System, Model: 300LOct 12, 2017
275 days to decisionK170085 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k170085/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Jan 10, 2017
Decision date	Oct 12, 2017
Days to decision	275 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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