

**K210468 SC1 Handheld Ultrasound Imaging System (Model: SC1)**

Jul 23, 2021  
157 days to decision

K210468 · Product code: **IYO** · Radiology  
Source: <https://www.510kdatabase.net/k210468/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Feb 16, 2021
Decision date	Jul 23, 2021
Days to decision	157 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Fcu Co., Ltd.</b>
Location	Yuseong-Gu, KR
Contact	Lee Hee Yeon
510(k) history	2 submissions · 2 cleared · 2021-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k210468/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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