

K233579 SC1 Handheld Ultrasound Imaging system (Model: SC1)

Jun 26, 2024
232 days to decision

K233579 · Product code: **IYO** · Radiology
Source: <https://www.510kdatabase.net/k233579/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Nov 7, 2023
Decision date	Jun 26, 2024
Days to decision	232 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Fcu Co., Ltd.
Location	Yuseong-Gu, KR
Contact	Song Hyuk
510(k) history	2 submissions · 2 cleared · 2021-2024

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k233579/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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