

K222854 iTFlowMay 12, 2023
233 days to decisionK222854 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k222854/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Sep 21, 2022
Decision date	May 12, 2023
Days to decision	233 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Cardio Flow Design, Inc.
Location	Tokyo, JP
Contact	Teruyasu Nishino
510(k) history	1 submissions · 1 cleared · 2023-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k222854/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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