FDA 510(k) Premarket Notification

K230823 AusculThing ACC

CLEARED

Jul 12, 2023
110 days to decision

K230823 · Product code: **DQD** · Cardiovascular
Source: https://www.510kdatabase.net/k230823/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stethoscope, Electronic (DQD)
Date received	Mar 24, 2023
Decision date	Jul 12, 2023
Days to decision	110 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Ausculthing OY**
Location	Espoo, FI
Contact	Jani Virtanen
510(k) history	1 submissions · 1 cleared · 2023-2023

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k230823/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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