

K230613 SKEEPERAug 2, 2023
149 days to decisionK230613 · Product code: **DQD** · CardiovascularSource: <https://www.510kdatabase.net/k230613/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stethoscope, Electronic (DQD)
Date received	Mar 6, 2023
Decision date	Aug 2, 2023
Days to decision	149 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Smartsound Corporation
Location	Seoul, KR
Contact	Jungho Lee
510(k) history	1 submissions · 1 cleared · 2023-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k230613/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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