FDA 510(k) Premarket Notification

K230613 SKEEPER

CLEARED

Aug 2, 2023
149 days to decision

K230613 · Product code: **DQD** · Cardiovascular
Source: 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