

K231104 ABPMproNov 27, 2023
222 days to decisionK231104 · Product code: **DSH** · Cardiovascular
Source: <https://www.510kdatabase.net/k231104/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Recorder, Magnetic Tape, Medical (DSH)
Date received	Apr 19, 2023
Decision date	Nov 27, 2023
Days to decision	222 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Somnomedics GmbH
Location	Washington, DC, US
Contact	Timo Gehring
510(k) history	7 submissions · 7 cleared · 2007-2024

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