

K250860 BreatheBand® (Model 1000)Oct 2, 2025
195 days to decisionK250860 · Product code: **BYI** · Anesthesiology
Source: <https://www.510kdatabase.net/k250860/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Percussor, Powered-electric (BYI)
Date received	Mar 21, 2025
Decision date	Oct 2, 2025
Days to decision	195 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Exemplar Medical, LLC
Location	Kansas City, MO, US
Contact	Christian Moore
510(k) history	1 submissions · 1 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250860/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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