

K233337 Freespira Breathing SystemApr 24, 2025
573 days to decisionK233337 · Product code: **SEN** · Neurology
Source: <https://www.510kdatabase.net/k233337/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Biofeedback For Adjunctive Treatment Of Symptoms Associated With Stress And Anxiety (SEN)
Date received	Sep 29, 2023
Decision date	Apr 24, 2025
Days to decision	573 days
Third-party review	No
Combination product	No
PCCP authorized	No

APPLICANT

Company	Freespira, Inc.
Location	Kirkland, WA, US
Contact	Thomas Simon
510(k) history	1 submissions · 1 cleared · 2025-2025

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