

K180173 FreespiraAug 23, 2018
213 days to decisionK180173 · Product code: **HCC** · Neurology
Source: <https://www.510kdatabase.net/k180173/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Biofeedback (HCC)
Date received	Jan 22, 2018
Decision date	Aug 23, 2018
Days to decision	213 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Palo Alto Health Sciences, Inc.
Location	Sunnyvale, CA, US
Contact	Simon Thomas
510(k) history	2 submissions · 2 cleared · 2013-2018

REGULATORY CONSULTANT

Consulting firm	Acknowledge Regulatory Strategies, LLC
Contact	Allison Komiyama

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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