

K201473 ExoAtlet-IIJul 16, 2021
408 days to decisionK201473 · Product code: **PHL** · Neurology
Source: <https://www.510kdatabase.net/k201473/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Exoskeleton (PHL)
Date received	Jun 3, 2020
Decision date	Jul 16, 2021
Days to decision	408 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Exoatlet Asia Co. , Ltd.
Location	Denver, CO, US
Contact	Bret Bostock
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Acknowledge Regulatory Strategies, LLC
Contact	Allison C Komiyama

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

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