

**K213519 Rune Labs Tremor Transducer System**Jun 10, 2022  
219 days to decisionK213519 · Product code: **GYD** · Neurology  
Source: <https://www.510kdatabase.net/k213519/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transducer, Tremor (GYD)
Date received	Nov 3, 2021
Decision date	Jun 10, 2022
Days to decision	219 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Rune Labs, Inc.</b>
Location	San Francisco, CA, US
Contact	Brian Pepin
510(k) history	1 submissions · 1 cleared · 2022-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Anacapa Clinical Research, Inc.</b>
Contact	Courtney Lane

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k213519/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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