FDA 510(k) Premarket Notification

# K213519 Rune Labs Tremor Transducer System

**CLEARED**

Jun 10, 2022
219 days to decision

K213519 · 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

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

## REGULATORY CONSULTANT

| | |
|---|---|
| Consulting firm | **Anacapa Clinical Research, Inc.** |
| Contact | Courtney Lane |

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