

**K253055 Sine Monitoring Parkinson's Disease Tremor
Dyskinesia Apple Watch ("SMPDTDAW")**Jun 17, 2026
268 days to decisionK253055 · Product code: **GYD** · Neurology
Source: <https://www.510kdatabase.net/k253055/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transducer, Tremor (GYD)
Date received	Sep 22, 2025
Decision date	Jun 17, 2026
Days to decision	268 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Nordic Kinetics AB
Location	Lund, SE
Contact	Jakob V. E. Gerstl
510(k) history	1 submissions · 1 cleared · 2026-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253055/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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