June 17, 2026

Nordic Kinetics AB
Jakob V. E. Gerstl
CEO
Skolgatan 3B
Lund, 223 61
Sweden

Re: K253055
Trade/Device Name: Sine Monitoring Parkinson's Disease Tremor Dyskinesia Apple Watch ("SMPDTDAW")
Regulation Number: 21 CFR 882.1950
Regulation Name: Tremor transducer
Regulatory Class: Class II
Product Code: GYD, NXQ
Dated: May 17, 2026
Received: May 18, 2026

Dear Jakob V. E. Gerstl:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Patrick Antkowiak -S

for
Jay Gupta
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional, and
Neurodiagnostic Devices
OHT5: Office of Neurological and
Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253055

Please provide the device trade name(s).

Sine Monitoring Parkinson's Disease Tremor Dyskinesia Apple Watch ("SMPDTDAW")

Please provide your Indications for Use below.

Sine Monitoring Parkinson's Disease Tremor Dyskinesia Apple Watch is intended to quantifykinematics of movement disorder symptoms including tremor and dyskinesia, in adults (45 years ofage or older) with mild to moderate Parkinson's disease.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) Summary

1. Submitter

- **Nordic Kinetics AB**
- Swedish Organization number ("Organisationsnummer"): 559521-2373
- FDA Org ID: 808426
- Address: Bantorget 2, 222 29, Lund, Sweden
- Contact person: Jakob V. E. Gerstl, MBBS, MPH
- Phone: +1 (617) 961 95 90
- Email: jgerstl@nordickinetics.com

- Date prepared: June 15, 2026

2. Device

- Trade name: Sine Monitoring Parkinson's Disease Tremor Dyskinesia Apple Watch
- Common name: Tremor transducer
- Classification name: Transducer, Tremor
- Regulatory Class: Class II
- Regulation name: 882.1950
- Product Code: GYD, NXQ

3. Predicates

First legally marketed predicate device

- Predicate code: K213519
- Predicate trade name: Rune Labs Kinematics System
- Product code: GYD

Second legally marketed predicate device

- Predicate code: K220820
- Predicate trade name: Parky App ("Parky")
- Product code: GYD, NXQ, ISD

4. Device description

Sine Monitoring Parkinson's Disease Tremor Dyskinesia Apple Watch (the "Device" or "SMPDTDAW") is a software application intended to collect derived probability scores of Parkinson's disease tremor and dyskinesia using the clinically validated toolkit for Apple Watch (developed by Apple) called Motor Fluctuations Monitor for Parkinson's Disease ("MM4PD"). The processed data subsequently are uploaded to the Nordic Kinetics Cloud Platform using the internet connection of the Apple Watch.

5. Indications for Use

Sine Monitoring Parkinson’s Disease Tremor Dyskinesia Apple Watch is intended to quantify kinematics of movement disorder symptoms including tremor and dyskinesia, in adults (45 years of age or older) with mild to moderate Parkinson's disease.

6. Comparison of Technological Characteristics and Indications of Use to Predicates

Like both the Rune Labs Kinematics System (K213519) and Parky (K220820) (together the "Predicates"), SMPDTDAW utilizes MM4PD to analyze Apple Watch sensor data to derive probability scores of Parkinson's Disease tremor and dyskinesia. Both predicates are like SMPDTDAW intended to be used to quantify kinematics of movement disorder symptoms including tremor and dyskinesia, in adults (45 years of age or older) with mild to moderate Parkinson's disease.

Similar to SMPDTDAW, Parky has a function allowing patients to document medication schedules and send reminders; of note, the product code NXQ "medication reminder" is not subject to 510(k) notification. There are no differences in the working principles that could affect the safety or accuracy of the Device compared to the Predicates. SMPDTDAW is compared to the Predicates in Table 1.

Table 1. Comparison between SMPDTDAW and the Predicates.

Characteristic	SMPDTDAW (Subject Device)	Parky App (K220820)	Rune Labs Kinematic System (K213519)
Regulation Number	21 CFR 882.1950	21 CFR 882.1950	21 CFR 882.1950
Product Code(s)	GYD, NXQ	GYD, NXQ, ISD	GYD
Device Class	Class II	Class II	Class II
Indications for Use	Quantify kinematics of tremor and dyskinesia in adults with mild to moderate Parkinson's disease (≥ 45 yrs)	Same	Same
Intended Use	Monitor and quantify tremor and dyskinesia symptoms using Apple Watch sensors and display trends over time	Same	Same
Target Population	Adults ≥ 45 yrs with mild to moderate Parkinson's	Same	Same
Wearable Component	Apple Watch	Apple Watch	Apple Watch
Motion Sensing Method	MM4PD (Apple Watch accelerometer)	MM4PD API	MM4PD API
Data Processing	Smartphone app + optional cloud-based backend	iPhone app	Apple Watch + Cloud Backend
Output Format	Tremor and dyskinesia profiles (time-series, reports)	Daily/weekly/monthly reports	Visualized clinician dashboard
Medication Reminders	Yes	Yes	No
Step Count Feature	Not included	Yes	Not included
Data Transmission	Apple Watch → Cloud	Same	Apple Watch → Cloud

Characteristic	SMPDTDAW (Subject Device)	Parky App (K220820)	Rune Labs Kinematic System (K213519)
Cybersecurity Approach	Local encryption, TLS for data transmission, secure APIs	Same	Cloud security + user device security
Software Validation	Per FDA June 2023 Guidance + IEC 62304	Older version	Older version
Clinical Validation of MM4PD	Powers et al., 2021[1]	Referenced	Referenced
Biocompatibility	Apple Watch contact materials	Same	Same
EMC / Electrical Safety	Uses Apple Watch compliance with IEC 62368-1 and EN 301 489 standards	Same	Same
Labeling	IFU with screenshots, symptom explanation, warnings	Same	Dashboard-based interface guidance

Abbreviations and acronyms: API = Application Programming Interface; CMS = Choreiform Movement Score; EMC = Electromagnetic Compatibility; FDA = U.S. Food and Drug Administration; IEC = International Electrotechnical Commission; IFU = Instructions for Use; MDS-UPDRS = Movement Disorder Society-Unified Parkinson's Disease Rating Scale; MM4PD = Motor Fluctuations Monitor for Parkinson's Disease; PD = Parkinson's Disease; SaMD = Software as a Medical Device; SMPDTDAW = Sine Monitoring Parkinson's Disease Tremor Dyskinesia Apple Watch; TLS = Transport Layer Security.

7. Non-clinical Test Summary

7.1 Software validation and verification

The software design, validation and verification were performed in accordance with IEC 62304:2006 which is harmonized with the requirements of *Content of Premarket Submissions for Device Software Functions* issued on June 14, 2023.

The documentation level was deemed to be basic as no hazards have been identified that could lead to serious injury or death from the use of the Device.

7.2 Cybersecurity

Nordic Kinetics has performed a cybersecurity risk assessment as described in *Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions* issued 27 June 2025 and implemented control measures to address the identified risks.

7.3 Software performance verification and validation testing

An end-to-end software performance and data integrity validation test was performed to verify that all software requirements are reliably implemented and that data fidelity is preserved end-to-end from Apple Watch MM4PD output, through transmission to the Cloud Platform, storage in the database, aggregation into daily/weekly/monthly reports, and graphical presentation in the Phone Application and Web Application.

Twelve pre-defined acceptance criteria were specified, covering automated unit testing across all four software components (547 tests), seven system-level tests (data transmission integrity, data storage accuracy, graphical display fidelity in Web and Phone Applications, report aggregation accuracy, offline resilience, and authentication/role-based access), seventeen manual test cases, full regression on the release candidate, and defect-register status.

7.4 Conclusions from non-clinical testing

All twelve pre-defined acceptance criteria were met. All 547/547 automated unit tests passed (100 %) across the Apple Watch Companion (10/10), Phone Application (48/48), Web Application (15/15), and Cloud Platform API (474/474). All seven system-level tests passed: 16,050 of 16,050 classification records were received with zero duplicates and zero corruption; field-by-field storage match was 100 %; every displayed data point in the Web and Phone Applications corresponded to a stored database record; independently re-computed daily aggregations matched displayed values within the ± 0.1 % floating-point rounding tolerance; no data loss occurred across an intentional offline interval exceeding four hours; and authentication and role-based access controls were correctly enforced.

All seventeen manual test cases passed, the full regression suite re-passed 547/547, and no critical or major defects remained open in the defect register. Software design, verification, and validation were conducted in accordance with IEC 62304:2006 and the FDA guidance *Content of Premarket Submissions for Device Software Functions* (June 14, 2023). The cybersecurity risk assessment, controls, architecture views, SBOM, and management plan were prepared in accordance with the FDA guidance *Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions* (June 27, 2025). Nordic Kinetics concludes that the non-clinical testing demonstrates that SMPDTDAW reliably implements all software requirements, preserves data fidelity end-to-end, and is as safe and as effective as the identified predicate devices for its proposed intended use.

8. Clinical Tests Summary

8.1 Study overview

MM4PD was developed by Apple and validated in three clinical studies with a total 343 unique participants with diagnosed PD, of whom 61 experienced dyskinesia.[1] A total of 171 elderly persons without a PD diagnosis were included in the study as control.

The data from the first pilot study, involving 118 patients, was used to design the API. A longitudinal study over a six months period involved 225 patients, and the data was used to further design and to validate MM4PD. The 171 control persons were tracked over 12 months in a third longitudinal control study. A summary of the demographic of the participants is shown in Table 2.

	Pilot study PD patients in-clinic + 1 week live-on	Longitudinal patient study PD patients long-term live-on	Longitudinal control study Elderly controls
Age [± Standard Dev]	68.1 yrs [±9.0]	71.4 yrs [±8.9]	74.7 yrs [±5.4]
Years with PD [± Standard Dev]	6.5 yrs [±5.6]	10.3 yrs [±6.5]	n/a
Gender	36 Female, 82 Male	69 Female, 156 Male	85 Female, 85 Male, 1 unknown
Most Affected Side	62 Right / 39 Left / 17 unspecified	105 Right / 120 Left	n/a
History of Tremor	-	166/225 Participants	n/a
History of Dyskinesia (History of Chorea)	-	94/225 Participants (66/94 with dyskinesia)	n/a
History of Freezing Gait	-	85/225 Participants	n/a
History of Slow Gait	-	172/225 Participants	n/a
		*self-reported history	

Table 2. Subject demographic across the three Powers Study cohorts (Pilot Study, Longitudinal Patient Study, Longitudinal Control Study). Reproduced from Powers et al. 2021[1] (Table 1 of the published article).

8.2 Displacement measurement accuracy

A healthy, control subject simulated tremor movements with varying amplitudes while wearing an Apple Watch in standing and seated positions. Six reflective markers were attached to the Apple Watch and tracked using the motion detection system Vicon. The Pearson correlation coefficient

between displacement measured by a motion capture system and the watch estimate was 0.98 in the control subject, with a mean signed error of −0.04 ± 0.17 cm.

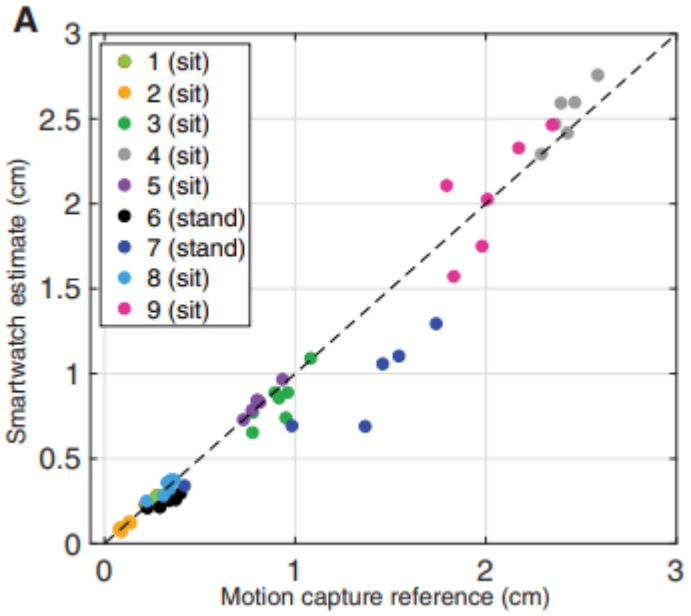

Figure 1. Motion capture correlation. Smartwatch displacement estimate (cm) plotted against the simultaneous motion-capture reference (cm) for nine simulated tremor sessions (subjects 1–9, seated or standing), with the dashed identity line. Pearson r = 0.98; mean signed error −0.04 ± 0.17 cm. Reproduced from Powers et al. 2021[1] (Fig. 3A).

8.3 Tremor assessment

MM4PD was designed to detect and classify the severity of tremor (based on displacements) as slight (< 0.1 cm), mild (0.1–0.6 cm), moderate (0.6–2.2 cm), strong (> 2.2 cm), or absent during each one-minute interval.

In the pilot study, three neurologists scored the tremor based on video recordings of the patient. In the longitudinal study, one neurologist with previous knowledge about the patient's medical history assessed the tremor severity in person. All ratings were made in accordance with the revised Movement Disorder Society's Unified Parkinson's Disease Rating Scale (MDS-UPDRS). The watch displacement measured correlated with the MDS-UPDRS tremor amplitude rating with a rank coefficient of 0.80 (see Figure 2).

In the pilot study, patients performed cognitive distraction tasks. MM4PD captured tremor in 97.7 % of cases where all neurologists agreed.

The median false positive rate over 43,300 measured hours in the longitudinal control study was 0.25 %. False positives occurred infrequently during targeted activities in young, healthy controls, such as manual teeth brushing (8 %) and playing a musical instrument (2 %).

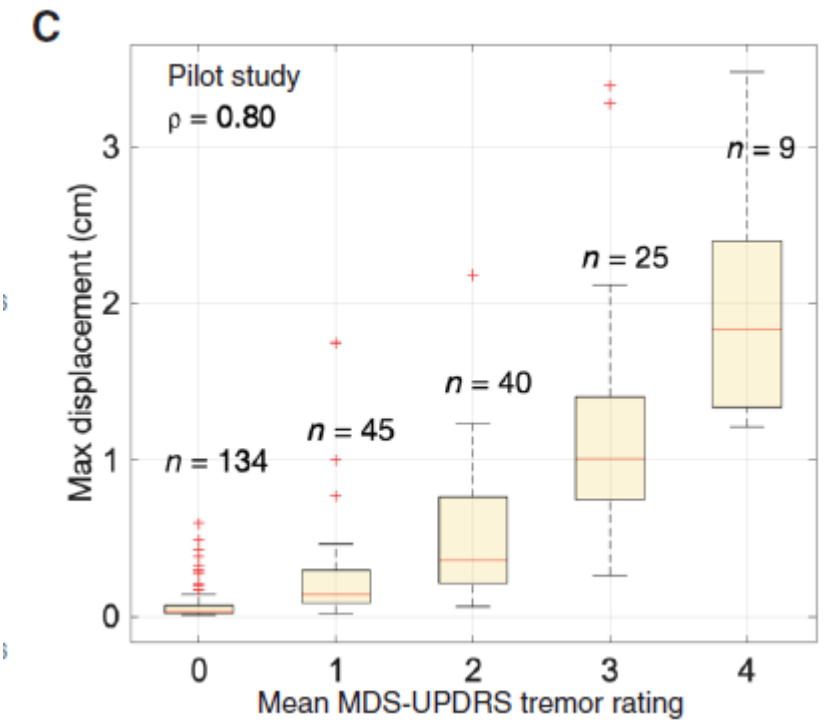

Figure 2. Displacement estimates from the smartwatch categorized by tremor rating. Pilot-study box plots of maximum smartwatch displacement (cm) against the mean MDS-UPDRS tremor rating (0–4); per-rating sample sizes n = 134, 45, 40, 25, 9. Spearman ρ = 0.80. Reproduced from Powers et al. 2021[1] (Fig. 3C).

8.4 Dyskinesia assessment

The choreiform movement score (CMS) that continuously evaluates the presence of dyskinesia was developed based on the recording of irregular jerky movements in patients with diagnosed chorea. The dyskinesia algorithm was designed and validated across the 343 patients diagnosed with PD (of whom 61 had dyskinesia) and the 171 elderly non-PD diagnosed controls.

The CMS calculated from data gathered during the pilot study was compared with dyskinesia ratings made by three MDS-certified experts during multiple MDS-UPDRS assessments. The CMS score showed significant differences ($P < 0.001$) for all pairwise comparisons based on a Wilcoxon rank sum test across three groups: (i) 65 subjects with confirmed absence of in-session dyskinesia by all three raters (89 tasks), (ii) 69 subjects with discordant dyskinesia ratings (109 tasks), and (iii) 19 subjects with confirmed dyskinesia across all three raters (22 tasks).

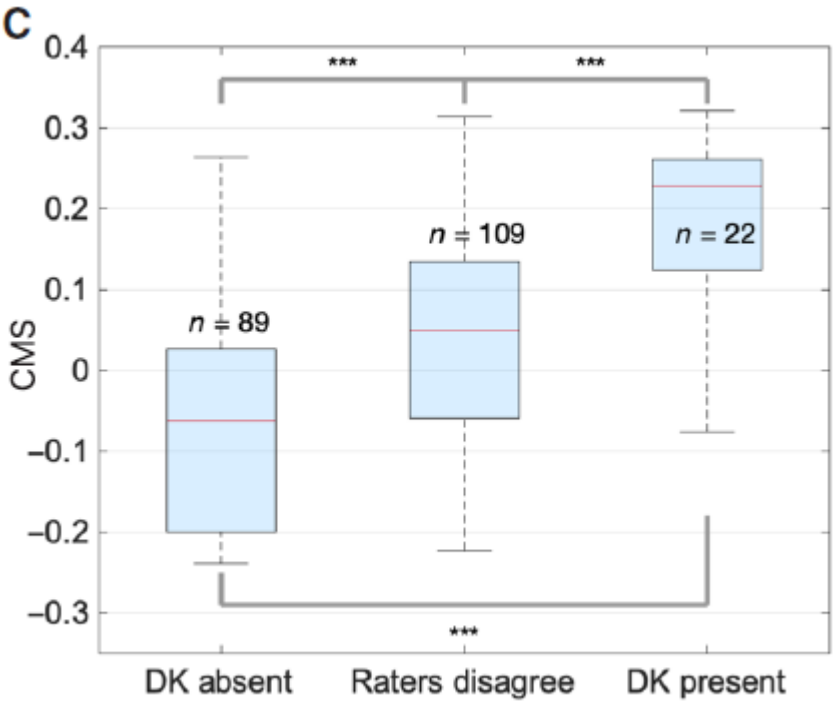

Figure 3. Chorea movement scores (CMS) computed during in-clinic cognitive distraction tasks in the pilot study, partitioned by expert rating: DK absent (n = 89 tasks), Raters disagree (n = 109 tasks), DK present (n = 22 tasks). All pairwise comparisons $P < 0.001$ (Wilcoxon rank sum test). Reproduced from Powers et al. 2021[1] (Fig. 4C).

As validation, the dyskinesia detected by MM4PD among 32 PD patients with diagnosed chorea was compared to the dyskinesia detected among 125 PD patients without diagnosed chorea. Dyskinesias were detected 10.7 ± 9.9 % of the time in the first group compared to 2.7 ± 2.2 % in the second group ($P < 0.001$, Wilcoxon rank sum test) (Figure 4). For further validation a hold-out dataset from the longitudinal patient study was analyzed separately. From this data set the dyskinesias were detected 5.9 ± 5.3 % of the time for the chorea group, which significantly differed from subjects with no reported dyskinesias (2.0 ± 2.2 %) ($P = 0.027$, Wilcoxon rank sum test) (Figure 4).

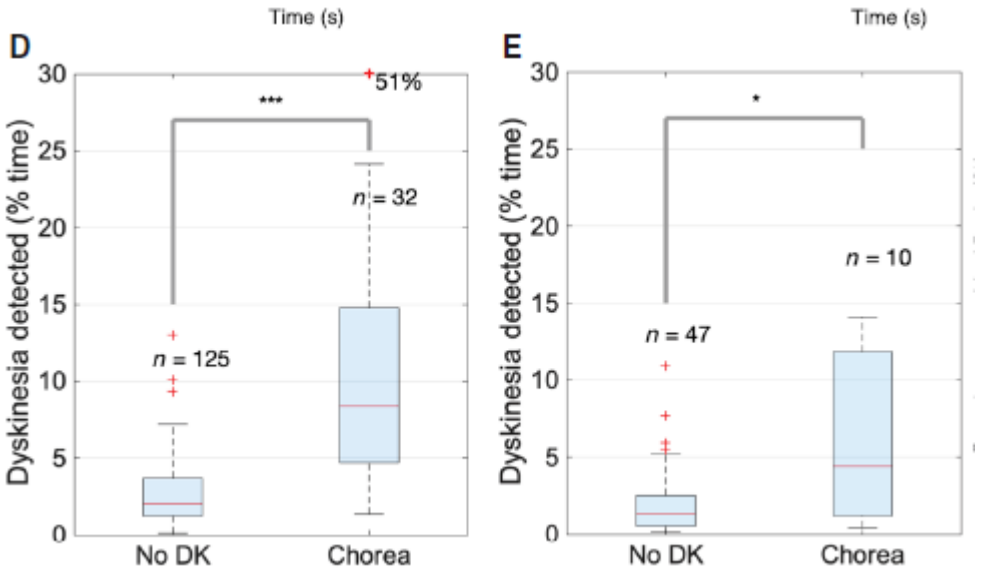

Figure 4. Dyskinesia detected (% of monitored time) compared between PD patients with diagnosed chorea and PD patients without diagnosed chorea. **Left (D, design set, all-day data):** No-DK group n = 125 (median ≈ 2 %); chorea group n = 32 (median ≈ 8 %); P < 0.001 (Wilcoxon rank sum test). **Right (E, hold-out set):** No-DK group n = 47; chorea group n = 10; P = 0.027 (Wilcoxon rank sum test). Reproduced from Powers et al. 2021[1] (Fig. 4D, E).

8.5 Conclusions from clinical testing

The clinical performance of the underlying tremor and dyskinesia detection algorithms used by SMPDTDAW is established by the Powers Study (Powers et al., Sci Transl Med, 2021), which validated the MM4PD algorithms across three sub-studies totaling 514 participants (343 patients with Parkinson's disease, of whom 61 had dyskinesia, and 171 elderly non-PD controls). Smartwatch tremor displacement correlated with motion-capture reference (Pearson r = 0.98) and with MDS-UPDRS tremor severity ratings (Spearman ρ = 0.80); mean daily tremor estimates correlated with MDS-UPDRS tremor constancy scores (Spearman ρ = 0.72) in both the design and the hold-out data sets. Median tremor false-positive rate in 43,300 hours of all-day data from elderly non-PD controls was 0.25 %. Choreiform movement scores significantly differentiated dyskinesia presence vs. absence (P < 0.001 for all pairwise comparisons), with a median dyskinesia false-positive rate of 2.0 % in elderly controls and a hold-out validation P = 0.027. Treatment-related symptom changes captured by MM4PD matched clinician expectations in 94 % of evaluated subjects (98 of 104). No serious adverse events were reported in any of the three studies. Because SMPDTDAW utilizes the MM4PD API in unmodified form (Nordic Kinetics does not modify the MM4PD algorithms, thresholds, or classification logic), the clinical performance results of the Powers Study apply directly to the SMPDTDAW outputs. This approach is consistent with the cited predicate devices (K213519 and K220820), each of which was cleared on the basis of the Powers Study without conducting additional clinical trials. Nordic Kinetics concludes that the clinical evidence demonstrates that SMPDTDAW is as safe and as effective as the identified predicate devices for its proposed intended use.

9. Substantial Equivalence Conclusion

SMPDTDAW has the same intended use as, and the same fundamental scientific technology and operating principles as, the cited predicate devices, the Rune Labs Kinematics System (K213519) and Parky (K220820). All three devices use the unmodified MM4PD API on Apple Watch hardware to derive tremor and dyskinesia probability scores in adults with mild-to-moderate Parkinson's disease, and present the resulting symptom profiles to clinicians for ongoing clinical assessment. Differences in technological characteristics (described in Section 6) do not alter the device's intended use and do not raise different questions of safety and effectiveness. The non-clinical performance testing summarized in Section 7 demonstrates that SMPDTDAW reliably implements all software requirements and preserves data fidelity end-to-end from MM4PD output to the user-facing graphical display, and the clinical performance evidence summarized in Section 8 demonstrates that the MM4PD algorithm consumed unchanged by SMPDTDAW performs as intended in the target population. Taken together, the information provided in this 510(k) Summary supports a determination that SMPDTDAW is substantially equivalent to the identified predicate devices and is as safe and as effective as those legally marketed devices for its proposed intended use.

References

1. Powers R, Etezadi-Amoli M, Arnold EM, et al. Smartwatch inertial sensors continuously monitor real-world motor fluctuations in Parkinson's disease. *Sci Transl Med.* Feb 3, 2021;13(579). doi:10.1126/scitranslmed.abd7865 ↩ ↩2 ↩3 ↩4 ↩5 ↩6 ↩7