



July 22, 2024

AlgoDx AB
Andreas Macura
QA
PO Box 559173-7985, Visiting address: Gotgatan 22A
Stockholm, 106 31
Sweden

Re: K240558
Trade/Device Name: Navoycads
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: PLB
Dated: February 28, 2024
Received: February 28, 2024

Dear Andreas Macura:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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.

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,

Robert T. Kazmierski -S

for

LCDR Stephen Browning

Assistant Director

DHT2A: Division of Cardiac

Electrophysiology, Diagnostics

and Monitoring Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K240558

Device Name
NAVOYCDS

Indications for Use (Describe)

NAVOYCDS is intended to be used with patient data from already cleared patient monitoring devices which measure respiratory rate, systolic blood pressure, and Glasgow Coma Scale (GCS) in adult patients being monitored in a healthcare facility. The device uses an algorithm to calculate a qSOFA score (also known as quickSOFA) which indicates adult patients with suspected infection who are at greater risk for a poor outcome. It uses three criteria, assigning one point for low blood pressure (SBP \leq 100 mmHg), high respiratory rate (\geq 22 breaths per min), or altered mentation (Glasgow coma scale $<$ 15).

NAVOYCDS is an adjunct to and is not intended to replace vital signs monitoring.

NAVOYCDS is intended to provide additional information for use during patient monitoring in a healthcare facility. NAVOYCDS is not intended for making clinical decisions regarding patient treatment or for diagnostic purposes.

The device is intended for an adult population.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Contact Details

21 CFR 807.92(a)(1)

Applicant Name	AlgoDx AB
Applicant Address	PO Box 559173-7985, Visiting address: Götgatan 22A Stockholm 106 31 Sweden
Applicant Contact Telephone	+46768668842
Applicant Contact	Mr. Andreas Macura
Applicant Contact Email	andreas.macura@algodx.com

Device Name

21CFR 807.92(a)(2)

Device Trade Name	NAVOYCDS
Common Name	Cardiac monitor (including cardiometer and rate alarm)
Classification Name	Multivariate Vital Signs Index
Regulation Number	870.2300
Product Code(s)	PLB

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	K230386
Predicate Trade Name (Primary Predicate is listed first)	SpassageQ
Product Code	PLB

Device Description Summary

21 CFR 807.92(a)(4)

NAVOYCDS consists of:

- A gateway module for handling clinical data supporting the HL7 format FHIR.
- A qSOFA score module to calculate patients' qSOFA scores and offer their last 72 hours history data.
- A web-based dashboard to render patients' qSOFA scores in a visually distinctive way depending on their value and enable intended users to view patients with suspected infection.

The NAVOYCDS system works in the following sequence:

- Receive patient data from the HL7 gateway system.
- Extract 3 vital signs from the patient data and store them in the database.

- The Glasgow Coma Scale (GCS) of a patient is stored in the database when a user submits it.
- NAVOYCDS calculates the qSOFA score automatically and stores the result in the database.
- NAVOYCDS delivers 3 vital signs, qSOFA score, GCS to users.
- The qSOFA score is presented in a visually distinctive way depending on the value and enables users to view patients with suspected infection.

Interpretation of qSOFA score:

The qSOFA score (also known as quickSOFA) is a bedside prompt that may identify patients with suspected infection who are at greater risk for a poor outcome. It uses three criteria, assigning one point for low blood pressure (SBP \leq 100 mmHg), high respiratory rate (\geq 22 breaths per min), or altered mentation (Glasgow coma scale $<$ 15). The score ranges from 0 to 3 points. The presence of 2 or more qSOFA points near the onset of infection is associated with a greater risk of death. These are outcomes that are more common in infected patients who may be septic than those with uncomplicated infection. Based upon these findings, the Third International Consensus Definitions for Sepsis recommends qSOFA as a simple prompt to identify infected patients who are likely to be septic.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

NAVOYCDS is intended to be used with patient data from already cleared patient monitoring devices which measure respiratory rate, systolic blood pressure, and Glasgow Coma Scale (GCS) in adult patients being monitored in a healthcare facility. The device uses an algorithm to calculate a qSOFA score (also known as quickSOFA) which indicates adult patients with suspected infection who are at greater risk for a poor outcome. It uses three criteria, assigning one point for low blood pressure (SBP \leq 100 mmHg), high respiratory rate (\geq 22 breaths per min), or altered mentation (Glasgow coma scale $<$ 15).

NAVOYCDS is an adjunct to and is not intended to replace vital signs monitoring.

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The device is intended for an adult population.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use are the same.

Technological Comparison

21 CFR 807.92(a)(6)

The subject device has the same technological characteristics as the predicate device, apart from alarm functionality. Both devices are software only devices, which provide the qSOFA score using vital signs and GCS.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

The following performance data were provided in support of the substantial equivalence determination.

Non-clinical Performance Testing involved system-level tests, performance tests and safety testing based on hazard analysis.

A cybersecurity documentation package has been established in accordance with the FDA Guidance Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions (September 2023).

In addition to the verification and validation testing activities executed by AlgoDx to establish the performance and functionality of NAVOYCDS, several standards were utilized:

ISO 14971:2019, Medical devices - Application of risk management to medical devices

IEC 62304:2006+A1:2015, Medical device software - Software life-cycle processes

IEC 62366-1:2015, Medical devices - Application of usability engineering to medical devices

IEC 82304-1 Edition 1.0 2016-10, Health software - Part 1: General requirements for product safety

IEC 81001-5-1 Edition 1.0 2021-12 Health software and health IT systems effectiveness and security - Part 5-1: Security - Activities in the product life cycle

ANSI/AAMI/IEC 60601-1-8:2006/A2:2021, General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems,

Amendment 2

Clinical Performance Testing was not needed in this 510(k) to support the substantial equivalence of the subject device to the predicate device.

The new device does not raise different questions of safety and effectiveness, and the testing performed demonstrated that the device is substantially equivalent to the predicate device.