June 15, 2023

Spass Inc.
% Edward Park
CEO
Radios LLC
4408 Tortuga Ln
McKinney, Texas 75070

Re: K230386
Trade/Device Name: SpassageQ
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: PLB
Dated: May 17, 2023
Received: May 17, 2023

Dear Edward Park:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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
Division of Cardiac Electrophysiology,
Diagnostics, and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230386

Device Name
SpassageQ

Indications for Use *(Describe)*

The SpassageQ 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 patients being monitored in a healthcare facility. The device provides qSOFA score (also known as quickSOFA) which indicates 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≤100 mmHg), high respiratory rate (≥22 breaths per min), or altered mentation (Glasgow coma scale<15).

The SpassageQ is an adjunct to and is not intended to replace vital signs monitoring. The device is intended to provide additional information for use during patient monitoring in a healthcare facility. The device 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.

Section 5. 510(K) Summary

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR Part 807, this information serves as a 510k Summary for the use of the SpassageQ .

1. SUBMITTER

Submitter Name:	Spass Inc.
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E-mail address:	lightenbridge@gmail.com

2. DEVICE

Device Name:	SpassageQ
Common Name:	Vital Sign Analysis Software
Classification Name:	Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Product Code	PLB
Regulation Number:	21 CFR 870.2300
Regulatory Class:	Class II
Classification Panel:	Cardiovascular

3. PREDICATE DEVICE

510(k) number:	K183282
Trade name:	Biovitals Analytics Engine
Product Code / Classification:	PLB / Class II, 21 CFR 870.2300
Company Name:	Biofourmis

4. DEVICE DESCRIPTION

The SpassageQ consists of:

- An automated algorithm to calculate data and generate qSOFA score and alarm when it is needed.
- An HL7 message receiver to handle incoming connection attempts from HL7 gateway systems, parse HL7 messages, and check the validity of HL7 messages.
- 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 be notified of patients with suspected infection.

The SpassageQ system works in the following sequence:

- Receive patient data from the HL7 gateway system.
- Extract 6 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.
- SpassageQ calculates the qSOFA score automatically and stores the result in the database.
- SpassageQ delivers 6 vital signs, qSOFA score, GCS to users.
- When the patient's qSOFA score is 2 points or higher, the users are notified of the patient through a visual alarm, and the alarm shall be reviewed by the qualified practitioner.

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≤100 mmHg), high respiratory rate (≥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.

5. INDICATIONS FOR USE

The SpassageQ 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 patients being monitored in a healthcare facility. The device provides qSOFA score (also known as quickSOFA) which indicates 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≤100 mmHg), high respiratory rate (≥22 breaths per min), or altered mentation (Glasgow coma scale<15).

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

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

The device is intended for an adult population.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Features	Proposed Device SpassageQ	Predicate Device Biovitals Analytics Engine	Comparison
General Characteristics			
Applicant	Spass	Biofourmis	-
510(k) Number	K230386	K183182	-
Classification	Class II, 21 CFR 870.2300	Class II, 21 CFR 870.2300	Similar
Product code	PLB	PLB	Similar
Intended Use	Patient Monitor (with alarm)	Patient Monitor (without alarms)	Similar except alarming feature
Indications for Use	The SpassageQ is intended to be used with patient data from already cleared patient monitoring devices which measure including respiratory rate, systolic blood pressure, and Glasgow Coma Scale (GCS) in patients being monitored in a healthcare facility. The device provides the qSOFA score (also known as quickSOFA) which indicates 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≤100 mmHg), high respiratory rate (≥22 breaths per min), or altered mentation (GCS<15). The SpassageQ is an adjunct to and is not intended to replace vital signs monitoring. The SpassageQ is intended to provide additional information for use during patient monitoring in a healthcare facility. The SpassageQ is not intended for making clinical decisions regarding patient	The Biovitals Analytic Engine (BA Engine) is intended to be used with continuous biometric data from already cleared sensors measuring heart rate, respiratory rate, and activity in ambulatory patients being monitored in a healthcare facility or at home, during periods of minimal activity. The device learns the correlation between multiple vital signs during the patient′s daily activity and builds an individualized biometric signature which is dynamically updated based on incoming data. The device computes a time series Biovitals Index (BI), which reflects changes in the patient′s measured vital signs from their measured baseline, which is derived from the individualized biometric signature of the patient. The BA Engine is a cloud-based software engine, intended to be an adjunct to and is not intended to replace vital signs monitoring. The BI is intended for daily intermittent, retrospective review by a qualified practitioner. The BA	Similar Both devices are intended to provide an index to a physician based on a patient′s vital signs, and to provide additional information during patient monitoring. Neither device is intended to replace vital signs monitoring, nor to provide a diagnosis to the physician.

Features	Proposed Device SpassageQ	Predicate Device Biovitals Analytics Engine	Comparison
	treatment or for diagnostic purposes. The device is intended for an adult population.	Engine is intended to provide additional information for use during routine patient monitoring. The BI is not intended for making clinical decisions regarding patient treatment or for diagnostic purposes. The device is intended for an adult population.	
Patient Population & Environment	Bedside | Non-pediatric	Ambulatory | Non-pediatric	Intended for the same population but under different environment It does not raise new questions of safety and effectiveness.
Technological Characteristics			
Components	Intranet Web-based Software only	Cloud-based software only	Similar All they are standalone software device. The difference is their operating platform. These minor difference does not raise new questions of safety and effectiveness.
Index Produced	Non-linear combination of vital parameters	Non-linear combination of vital parameters	Similar
Index Meaning	Index represents how different the relationships among the patient′s vital signs are with respect to normality. The presence of 2 or more qSOFA points indicates patients with suspected infection according to the Third International Consensus Definitions for Sepsis.	Index represents how different the relationships among the patient′s vital signs are with respect to normality. A BI less than or equal to 0.3 indicates that there has been little or no change in the relationship among the patient′s vital signs as compared to baseline. A BI value greater than 0.3 and less than or equal to 0.7 reflects moderate change, and a BI value greater than 0.7 reflects significant change in the	Similar While the devices have a different interpretation of the index, the usage of the index is similar, not raising new questions of safety and effectiveness.

Features	Proposed Device SpassageQ	Predicate Device Biovitals Analytics Engine	Comparison
		relationship among the patient′s vital signs as compared to baseline.	
Index Algorithm Normality	Normality is defined as the patient′s qSOFA assessment result (qSOFA score < 2)	Normality is defined as the patient′s own baseline.	Similar While the index used for getting results are not the same, it still reflects the same relationship among vital signs. This difference does not raise new questions of safety and effectiveness.
Index Display	Single numeric value of latest index Table	Single numeric value of latest index Trend graphs	Similar It does not raise different questions of safety and effectiveness.
Vital Signs Data Source	Vital sign data stored in the database which are from FDA cleared Patient Monitors	FDA cleared Patient Monitors and Clinical Information Systems	Similar The subject device uses data indirectly from FDA cleared patient monitors by obtaining the data through integration with HL7 gateway system. The predicate device enables use of data captured directly from FDA cleared patient monitors. Since the actual data source is the same, this difference does not raise new questions of safety and effectiveness.
Alarm System	Yes	No	Different

7. PERFORMANCE DATA

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

Non-clinical Performance

Testing involves system-level tests, performance tests and safety testing based on hazard analysis. Cybersecurity issues have been addressed. In addition to the verification and validation testing activities executed by Spass Inc. to establish the performance and functionality of SpassageQ and the predicate devices, 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 60601-1-6:2010, General requirements for basic safety and essential performance - Collateral standard: Usability

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

IEC 60601-1-8:2020, Medical Electrical Equipment - Part 1-8: General Requirements For Basic Safety And Essential Performance - Collateral Standard: General Requirements, Tests And Guidance For Alarm Systems In Medical Electrical Equipment And Medical Electrical Systems

Clinical Performance

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

8. CONCLUSIONS

The subject device SpassageQ uses the same and similar technology that is used in the predicate K183282 device's Biovitals Analytics Engine. Differences between the proposed device and the predicate device do not raise new types of questions regarding safety and effectiveness, and performance testing supports that the proposed device can be used as safely and as effectively for the proposed indications for use as the predicate device. The SpassageQ is considered to be substantially equivalent to the predicate K183282.