July 14, 2022

Fifth Eye Inc.
℅ Donna-Bea Tillman
Senior Consultant
Biologics Consulting
1555 King Street, Suite 300
Alexandria, Virginia 22314

Re: K221203
Trade/Device Name: AHI System
Regulation Number: 21 CFR 870.2220
Regulation Name: Adjunctive hemodynamic indicator with decision point
Regulatory Class: Class II
Product Code: QNV,QNL
Dated: June 17, 2022
Received: June 21, 2022

Dear Donna-Bea Tillman:

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,

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.*

Submission Number *(if known)*

K221203

Device Name

AHI System (v 2.2.0)

Indications for Use *(Describe)*

The AHI System is intended for use by healthcare professionals managing patients 18 years or older who are receiving continuous physiological monitoring with electrocardiography (ECG) in hospitals.

AHI provides a frequently updated binary output over time based on pattern analysis of a lead-II ECG waveform intended to describe a patient's hemodynamic status and indicate if a patient is showing signs of hemodynamic stability or instability. Signs of hemodynamic instability (HI) are defined as hypotension (systolic blood pressure <90 mmHg or mean arterial pressure (MAP) <70 mmHg) combined with tachycardia (heart rate ≥ 100 bpm).

AHI-PI provides the clinician with physiological insight into a patient's likelihood of a future episode of HI. An episode of HI is defined as 10 continuous minutes or more where HI is present.

The goal of this adjunctive monitoring method is to enable identification of patients who are showing HI or are likely to experience a future episode of HI, and to allow clinicians an opportunity to increase vigilance. This device is intended for adjunctive use with other physical vital sign parameters and patient information and is not intended to independently direct therapy.

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.**

# 510(k) Summary

Prepared on: 2022-06-14

## Contact Details

21 CFR 807.92(a)(1)

| | |
|---|---|
| Applicant Name | Fifth Eye Inc. |
| Applicant Address | 110 Miller Avenue, Suite 300 Ann Arbor MI 48104 United States |
| Applicant Contact Telephone | 734-260-4800 |
| Applicant Contact | Ms. Jennifer Baird |
| Applicant Contact Email | jbaird@fiftheye.com |
| Correspondent Name | Biologics Consulting |
| Correspondent Address | 1555 King Street, Suite 300 Alexandria VA 22314 United States |
| Correspondent Contact Telephone | (410) 531- 6542 |
| Correspondent Contact | Dr. Donna-Bea Tillman |
| Correspondent Contact Email | dtillman@biologicsconsulting.com |

## Device Name

21 CFR 807.92(a)(2)

| | |
|---|---|
| Device Trade Name | AHI System (v 2.2.0) |
| Common Name | Adjunctive hemodynamic indicator with decision point |
| Classification Name | Adjunctive Hemodynamic Indicator With Decision Point |
| Regulation Number | 870.2220 |
| Product Code | QNV |

## Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

| Predicate # | Predicate Trade Name (Primary Predicate is listed first) | Product Code |
|---|---|---|
| K212219 | AHI System | QNV |

## Device Description Summary

21 CFR 807.92(a)(4)

The AHI System is a multiparameter system designed to meet clinicians' need to identify patient hemodynamic status and predict patient hemodynamic instability episodes using two analytics:
1. Analytic for Hemodynamic Instability (AHI): Utilizing data from a single existing lead of a non-invasive electrocardiograph (ECG), AHI analyzes heart rate variability (HRV) and ECG morphology features to rapidly detect signs of hemodynamic stability or instability and categorize each window of data as either "AHI Stable" or "AHI Unstable." Time trending of AHI outputs is also provided.

2. Analytic for Hemodynamic Instability Predictive Indicator (AHI-PI): Utilizing AHI outputs from up to the most recent 30 minutes of ECG data, AHI-PI indicates the likelihood of a future episode of hemodynamic instability, defined as ten continuous minutes or more where signs of hemodynamic instability are present.

## Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The AHI System is intended for use by healthcare professionals managing patients 18 years or older who are receiving continuous physiological monitoring with electrocardiography (ECG) in hospitals.

AHI provides a frequently updated binary output over time based on pattern analysis of a lead-II ECG waveform intended to describe a patient's hemodynamic status and indicate if a patient is showing signs of hemodynamic stability or instability. Signs of hemodynamic instability (HI) are defined as hypotension (systolic blood pressure <90 mmHg or mean arterial pressure (MAP) <70 mmHg) combined with tachycardia (heart rate ≥ 100 bpm).

AHI-PI provides the clinician with physiological insight into a patient's likelihood of a future episode of HI. An episode of HI is defined as 10 continuous minutes or more where HI is present.

The goal of this adjunctive monitoring method is to enable identification of patients who are showing HI or are likely to experience a future episode of HI, and to allow clinicians an opportunity to increase vigilance. This device is intended for adjunctive use with other physical vital sign parameters and patient information and is not intended to independently direct therapy.

## Indications for Use Comparison

21 CFR 807.92(a)(5)

The subject device and predicate device have identical indications for use statements.

## Technological Comparison

21 CFR 807.92(a)(6)

Technological Characteristics: The subject device and predicate device have very similar technological characteristics. The only difference is a minor modification to the user interface to allow users to contraindicate only the exceptions for whom contraindications apply, rather than having to proactively assert "not contraindicated" on all patients.

## Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Software: Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a moderate level of concern. Testing was conducted to ensure the AHI System works as designed.