

**DE NOVO CLASSIFICATION REQUEST FOR
GILI PRO BIOSENSOR (ALSO KNOWN AS "GILI BIOSENSOR SYSTEM")**

REGULATORY INFORMATION

FDA identifies this generic type of device as:

Hardware and software for optical camera-based measurement of pulse rate, heart rate, breathing rate, and/or respiratory rate. The device uses an optical sensor system and software algorithms to obtain and analyze video signal and estimate pulse rate, heart rate, respiratory rate and/or breathing rates. This device is not intended to independently direct therapy.

NEW REGULATION NUMBER: 21 CFR 870.2790

CLASSIFICATION: Class II

PRODUCT CODE: QOK

BACKGROUND

DEVICE NAME: Gili Pro BioSensor (also known as "Gili BioSensor System")

SUBMISSION NUMBER: DEN200038

DATE DE NOVO RECEIVED: June 12, 2020

SPONSOR INFORMATION:

ContinUse Biometrics Ltd.
HaBarzel 32B
Tel-Aviv, Israel, 6971048

INDICATIONS FOR USE

The Gili Pro BioSensor (Gili BioSensor System) includes an optical module that is intended to capture motion-vibration signals from an illuminated surface for assessment of physiological information. Such information, captured during spot-measurement, includes:

- Heart rate
- Respiratory rate

The device is indicated for use by or under the supervision of healthcare professionals for adult patients in a hospital, outpatient, or other medical care settings, or for clinical research purposes.

The device should be used while the subject is seated upright either in a chair or in a bed. The information stored on the system may be reviewed by qualified persons.

LIMITATIONS

When using the device, the subject should be wearing smooth clothing that is snug fitting or flattened against the chest during measurements.

The device is not intended for continuous vital signs monitoring.

The device is not intended to be used as an apnea monitor.

PLEASE REFER TO THE LABELING FOR A COMPLETE LIST OF WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS.

DEVICE DESCRIPTION

The Gili Pro BioSensor is an optical system consisting of a sensing unit and a mobile unit with a preinstalled software application. The optical sensing unit is an aluminum enclosure which houses a lithium ion battery, illuminating optics (laser projector and laser pointer), digital image sensor, range meter, and firmware to facilitate data processing. The illuminating optics are based on eye-safe lasers which are compliant with Class I laser product accessible emission limits. The sensing unit is connected via a USB cable to a mobile unit on which the mobile application is installed.

The system illuminates the subject via a low-powered near infra-red (NIR at ~780 nm) light beam while an image sensor module captures the back reflected light pattern by the light sensor. The laser pointer illuminates in the visible spectrum (~650 nm) to facilitate proper positioning of the sensor relative to the subject. Changes in the reflected light pattern are coupled with motions of the illuminated surface, which are affected by heart and breathing motions. Analysis of these patterns through the software application correlate with heart and respiratory rates, as part of vital signs assessment. The heart and respiratory rate values are displayed on the user interface of the mobile unit.



Figure 1. The Gili Pro Biosensor Sensing Unit



Figure 2. Example of HR and RR Values Displayed on the Mobile Unit

Device measurement ranges are 30-230 bpm for heart rate and 4-60 breaths per minute (BrPM) for respiratory rate, of which the ranges of 38-100 bpm (for HR) and 6-34 BrPM (for Resp) were validated via clinical testing.

SUMMARY OF NONCLINICAL/BENCH STUDIES

SHELF LIFE/STERILITY

The Gili Pro BioSensor is a non-sterile and reusable device. It is designed for non-contact measurements. The shelf-life of the device is 3 years. This shelf-life was determined based on specific storage conditions of the battery.

ELECTROMAGNETIC CAPABILITY & ELECTROMAGNETIC SAFETY

The following Electrical/ Mechanical/Thermal Safety, electromagnetic compatibility (EMC) and laser safety testing has been performed:

- IEC 60601-1:2005+ CORR. 1:2006 + CORR. 2:2007 + A1:2012, General requirements for basic safety and essential performance for medical electrical equipment
- IEC 60601-1-2:2014, Medical electrical equipment Part 1-2 – General requirements for basic safety and essential performance – Electromagnetic compatibility.
- IEC 60825-1, Safety of laser products

SOFTWARE

The Gili Pro BioSensor has a Moderate Level of Concern (LOC). Appropriate documentation was provided to support the validation of the software for a Moderate LOC in accordance with FDA's 2005 guidance titled, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The sponsor provided details on how the software algorithm measures heart and respiratory rate. The workflow and software handling of hardware error or failures were demonstrated.

Appropriate documentation was provided in accordance with FDA's 2014 guidance document titled "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices" to support adequate cybersecurity measures have been taken and will be monitored and updated throughout the device life cycle.

PERFORMANCE TESTING - BENCH

Non-clinical performance testing was conducted to verify device performance across the intended range of heart and respiratory rates for values beyond what was observed in the clinical study. A modified manikin was used to simulate chest motion-vibrations of heart sounds and gross chest movements. Verification of manikin outputs were performed using reference devices. This testing included situations with extreme heart and breathing frequencies and different environmental conditions (clothing color, clothing layers, lighting conditions, etc.) Combinations of various conditions were tested to simulate worse-case scenarios. Mixed model estimates show that the heart rate and respiratory rate measurements met acceptance criteria of (b) (4) for heart rate and (b) (4) breaths per minute (BrPM) for respiratory rate. Repeatability and reproducibility (R&R) testing was performed using the manikin test-rig to demonstrate that the device provides consistent measurements regardless of operator. Results of the R&R testing showed a mean difference between devices across all reference values of (b) (4), indicating strong repeatability and reproducibility for both heart rate and respiratory rate measurements.

HUMAN FACTORS/USABILITY

A human factors study was conducted with 21 representative users to evaluate the usability of the Gili BioSensor system. These users were asked to use the device to obtain a vital sign measurement on a subject mimicking behaviors expected of patients. Overall, users demonstrated successful operation of the device, through set-up and measurement of both heart rate and respiratory rate. The testing provided adequate assurance that the critical tasks could be performed without difficulty or use errors.

SUMMARY OF CLINICAL INFORMATION

The sponsor provided a clinical study protocol and results to support the safety and effectiveness of the device. The clinical performance study design was two-phase trial with 10 subjects in the pilot phase and 120 in the main, pivotal study. Patient recruitment was stratified by non-arrhythmia/arrhythmia subjects and included a variety of chest shapes (i.e. barrel-chested/COPD subjects), BMIs (31% of subjects considered obese), ages (range of 29 – 93 years), and a distribution of light and dark skin colors as measured by the Fitzpatrick scale.

The study included two co-primary analyses to assess the accuracy of heart rate for the population of non-arrhythmia subjects and respiratory rate for the general population of subjects, with and without arrhythmia. The secondary objective was to demonstrate equivalence of the Gili BioSensor System to the reference device on heart rate for the general population of subjects, with and without arrhythmia. Heart rate was compared to the gold standard reference ECG to determine heart rate and presence of arrhythmia. Respiratory rate was compared to clinician over-scored capnography.

The primary analysis found that the Gili Pro BioSensor meets the pre-specified acceptance criteria for both heart rate and respiratory rate. A mixed model estimates for the method comparison between Gili and the reference was utilized. Additionally, (b) (4) confidence intervals were calculated using the bootstrap re-sampling method. Heart rate for non-arrhythmia patients met the pre-specified acceptance criteria of (b) (4). The intercept was (b) (4) confidence interval of (b) (4). Respiratory rate in the general population was found to have an intercept of (b) (4) confidence interval of (b) (4), within the pre-specified performance criteria of (b) (4).

Secondary confirmatory analysis found that the device meets the pre-specified criteria for comparison to ECG heart rate in the broader population, including individuals with arrhythmias. The secondary endpoint analysis determined an intercept of (b) (4) confidence interval of (b) (4). This result was within the range of the pre-specified acceptance criteria of (b) (4) bpm. Supportive analysis comparing the heart rate of the Gili Pro BioSensor to an additional PPG reference device demonstrated the device's equivalence. Lastly, poolability and covariate analyses found no notable covariate effects.

With respect to safety outcomes, no adverse events were reported during the trial period, which was expected given the contactless nature of the device.

Pediatric Extrapolation

In this De Novo request, existing clinical data were not leveraged to support the use of the device in a pediatric patient population.

LABELING

The labeling includes a description of what the device measures and outputs to the user. A summary of the validation and verification data performed provides expected performance for intended use populations and environments. When using the device, the subject should be wearing smooth clothing that is snug fitting or flattened against the chest during measurement. Other patient conditions that may affect performance of the device are listed in the labeling. The labeling provides instructions on the system set-up, taking measurements, device maintenance, and troubleshooting.

The device is not a continuous monitor and is only intended for spot-check measurements of heart and respiratory rate. The reported accuracy of the system is described for both

measurements in accordance with what was measured in the clinical study. The device should not be used with any subject that require critical care or continuous vital sign monitoring. The system is not intended to detect the presence/absence of arrhythmias. The Gili BioSensor system is intended for use by appropriately trained healthcare professionals and should not be used by untrained lay users. The device is not intended to be the sole method of checking the physical health of a subject.

RISKS TO HEALTH

The table below identifies the risks to health that may be associated with use of hardware and software for optical camera-based measurement of pulse rate, heart rate, breathing rate, and/or respiratory rate and the measures necessary to mitigate these risks.

Identified Risks to Health	Mitigation Measures
Delayed or incorrect treatment due to erroneous output as a result of device malfunction or algorithm error	Software verification, validation, and hazard analysis Cybersecurity assessment Clinical data Labeling
Delayed or incorrect treatment due to user misinterpretation	Human factors assessment Labeling
Eye damage, burns, and related safety concerns due to illuminating optics	Non-clinical performance testing Labeling

SPECIAL CONTROLS

In combination with the general controls of the FD&C Act, the hardware and software for optical camera-based measurement of pulse rate, heart rate, breathing rate and/or respiratory rate is subject to the following special controls:

- (1) A software description and the results of verification and validation testing based on a comprehensive hazard analysis and risk assessment must include:
 - (i) A full characterization of the software technical parameters, including algorithms;
 - (ii) A description of all mitigations for user error or failure of any subsystem components (including signal detection, signal analysis, data display, and storage) on output accuracy; and
 - (iii) Software documentation must include a cybersecurity vulnerability and management process to assure software functionality.
- (2) Performance testing must demonstrate the safety of any illuminating optics.
- (3) Clinical data must be provided. This assessment must fulfill the following:
 - (i) The clinical data must be representative of the intended use population for the device. Any selection criteria or sample limitations must be fully described and justified.

- (ii) The assessment must demonstrate output consistency using the expected range of data sources and data quality encountered in the intended use population and environment.
 - (iii) The assessment must compare device output with a clinically accurate patient-contacting relevant comparator device in an accurate and reproducible manner.
- (4) A human factors and usability engineering assessment must be provided that evaluates the risk of improper measurement.
- (5) Labeling must include:
- (i) A description of what the device measures and outputs to the user;
 - (ii) Warnings identifying sensor acquisition factors or subject conditions or characteristics (garment types/textures, motion, etc.) that may impact measurement results;
 - (iii) Guidance for interpretation of the measurements, including a statement that the output is adjunctive to other physical vital sign parameters and patient information;
 - (iv) The expected performance of the device for all intended use populations and environments; and
 - (v) Robust instructions to ensure correct system setup.

BENEFIT-RISK DETERMINATION

The risks of the device are based on data collected in a clinical study described above.

The consequences of an incorrect reading would be a delay in the provision of care or unnecessary testing. The patient could suffer harm from the delay in providing care. However, the device has been validated to have clinically acceptable accuracy and the probability of a patient harm related to false results is minimum.

The probable benefits of the device are also based on data collected in a clinical study as described above.

The device can provide benefit as heart rate and respiratory rate values are obtained without personal contact with a healthcare worker. Remote monitoring provided by the device can minimize personnel exposure to the patient, reducing the risk of transmission of bacteria and other infectious agents. In addition, contactless data collection provides the opportunity for patient monitoring without contributing to patient discomfort from electrode pads typically attached to the patient.

The Gili Pro BioSensor provides comparable accuracy to other monitoring methods. Results were also assessed when specifically including patients experiencing arrhythmias and performance remained consistent. For basic vital sign monitoring in these settings, there is a high likelihood that the Gili Pro BioSensor device can offer significant advantages over existing alternatives.

Patient Perspectives

This submission did not include specific information on patient perspectives for this device.

Benefit/Risk Conclusion

In conclusion, given the available information above, for the following indication statement:

The Gili Pro BioSensor (Gili BioSensor System) includes an optical module that is intended to capture motion-vibration signals from an illuminated surface for assessment of physiological information. Such information, captured during spot-measurement, includes:

- Heart rate
- Respiratory rate

The device is indicated for use by or under the supervision of healthcare professionals for adult patients in a hospital, outpatient, or other medical care settings, or for clinical research purposes.

The device should be used while the subject is seated upright either in a chair or in a bed. The information stored on the system may be reviewed by qualified persons.

The probable benefits outweigh the probable risks for the Gili Pro BioSensor (also known as "Gili BioSensor System"). The device provides benefits and the risks can be mitigated by the use of general controls and the identified special controls.

CONCLUSION

The De Novo request for the Gili Pro BioSensor (also known as "Gili BioSensor System") is granted and the device is classified as follows:

Product Code: QOK

Device Type: Hardware and software for optical camera-based measurement of heart rate and respiratory rate

Regulation Number: 21 CFR 870.2790

Class: II