April 1, 2021

ContinUse Biometrics Ltd.
% Yarmela Pavlovic
Regulatory Consultant
Manatt, Phelps & Phillips, LLP
1 Embarcadero Center, 30th Floor
San Francisco, California 94111

Re: DEN200038
Trade/Device Name: Gili Pro BioSensor (also known as "Gili BioSensor System")
Regulation Number: 21 CFR 870.2790
Regulation Name: Hardware and software for optical camera-based measurement of pulse rate, heart rate, breathing rate, and/or respiratory rate
Regulatory Class: Class II
Product Code: QOK
Dated: June 12, 2020
Received: June 12, 2020

Dear Yarmela Pavlovic:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the Gili Pro BioSensor (also known as "Gili BioSensor System"), a prescription device under 21 CFR Part 801.109 with the following 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.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Gili Pro BioSensor (also known as "Gili BioSensor System"), and substantially equivalent devices of this generic

type, into Class II under the generic name, hardware and software for optical camera-based measurement of pulse rate, heart rate, breathing rate, and/or respiratory rate.

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.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On June 12, 2020, FDA received your De Novo requesting classification of the Gili Pro BioSensor (also known as "Gili BioSensor System"). The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Gili Pro BioSensor (also known as "Gili BioSensor System") into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the Gili Pro BioSensor (also known as "Gili BioSensor System") can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

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

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.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety

and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the hardware and software for optical camera-based measurement of pulse rate, heart rate, breathing rate, and/or respiratory rate they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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 FD&C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact Jennifer Shih at 301-796-5813.

Sincerely,

for William C. Macfarland -S

Digitally signed by William C. Macfarland -S
Date: 2021.04.01 10:33:12 -04'00'

Bram Zuckerman, M.D.
Director
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health