July 24, 2018

Flashback Technologies, Inc.
Paul Dryden
Consultant
80 Health Park Drive, Suite 20
Louisville, Colorado 80027

Re: K173929
Trade/Device Name: CipherOx CRI M1
Regulation Number: 21 CFR 870.2200
Regulation Name: Adjunctive Cardiovascular Status Indicator
Regulatory Class: Class II
Product Code: PPW
Dated: June 20, 2018
Received: June 21, 2018

Dear Paul Dryden:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shawn W. Forrest -A

Digitally signed by Shawn W. Forrest -A
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300403341, cn=Shawn W. Forrest -A
Date: 2018.07.24 21:36:58 -04'00'

for
Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K173929

Device Name

CipherOx™ CRI M1

Indications for Use *(Describe)*

The CipherOx™ CRI M1 is indicated for continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (measured by an SpO2 sensor),and the Compensatory Reserve Index (CRI), which trends changes in intravascular volume relative to the individual patient's response to hypovolemia.

For patients with a finger thickness of 0.3" to 1" in hospital and pre-hospital settings.

CRI trends with changes in intravascular volume relative to the individual patient's response to hypovolemia, and should only be used by qualified medical providers as an adjunct to rather than as a replacement for traditional hemodynamic measures. CRI is indicated for adults (19-36 years old) in the supine position under non-motion conditions and without cardiovascular disease. CRI has not been studied in trauma patients.

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

XX 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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Company: Flashback Technologies, Inc.
80 Health Park Drive, Suite 20
Louisville, CO 80027

Official Contact: Dr. Greg Grudic, CO-Founder, CO-President, CTO
Phone: 720-204-2575

Proprietary or Trade Name: CipherOx CRI™ M1

Common/Usual Name: Adjunctive cardiovascular status indicator

Classification Name: 21 CFR 870.2200
Procode – PPW
Adjunctive cardiovascular status indicator
Class II

Predicate Device: DEN160020- Flashback Technologies – CipherOx CRI™ Tablet

Device Description:
The CipherOx CRI™ M1 is a modification of the predicate device, the CipherOx CRI Tablet (DEN160020). The M1 is a smaller version of the Tablet that is designed for increased portability.

The CipherOx CRI™ M1 is a non-invasive, continuous, and multi-parameter monitor that displays SpO_2, HR, and the Compensatory Reserve Index (CRI). CRI™ is a physiologic parameter that trends changes in intravascular volume, which help to assess a patient's hemodynamic status.

The CRI™ algorithm trends intravascular volume using non-invasive arterial pulsatile waveform signals by continuously comparing extracted waveforms to a reference model. CipherOx™ CRI system operates on the photoplethysmograph (PPG) waveform used in pulse oximetry to estimate CRI.

The CipherOx CRI™ M1 incorporates:

1. CRI™ algorithm
2. Nonin pulse ox sensor (8000AA – K080255)
    a. The 8000AA is an off-the-shelf finger clip sensor. It is designed to be used with the Nonin OEM III pulse oximetry module integrated in the M1 User Interface Module.
3. M1 User Interface module which is a small, portable, battery powered unit that displays heart rate, SpO_2, and CRI™.
    a. It contains a color display, processor, and the Nonin OEM III internal pulse oximeter module.
        i. Nonin designed the OEM III specifically for integration into devices such as the M1. The OEM III converts analog signals from the attached finger sensor into a stream of digital data that provides heart rate, SpO_2, and PPG.

Indications for Use:
The CipherOx™ CRI M1is indicated for continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate (measured by an SpO_2 sensor), and the Compensatory Reserve Index (CRI), which trends changes in intravascular volume relative to the individual patient's response to hypovolemia.

For patients with a finger thickness of 0.3" to 1" in hospital and pre-hospital settings.

CRI trends with changes in intravascular volume relative to the individual patient's response to hypovolemia, and should only be used by qualified medical providers as an adjunct to rather than as a replacement for traditional hemodynamic measures. CRI is indicated for adults (19-36 years old) in the supine position under non-motion conditions and without cardiovascular disease. CRI has not been studied in trauma patients.

Patient Population:
Based upon the validation studies – supine adults (19-36 years old) under non-motion conditions excluding patients with cardiovascular diseases.

Environment of Use:
Hospital and pre-hospital settings. a
Contraindications:
The contraindications of the CipherOx™ CRI M1

- Do not use the device in an MR environment, in an explosive atmosphere, or on infant or neonatal patients.
- This device is not defibrillation proof per IEC 60601-1.

Predicate Device Comparison

Table 1 – Comparison to the Predicate

CHARACTERISTICS	**Subject Device "CipherOx CRI M1"**	**Predicate "CipherOx CRI Tablet" DEN160020**
Indications for Use	The CipherOx CRI M1is indicated for continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate (measured by an SpO_2 sensor), and the Compensatory Reserve Index (CRI), which trends changes in intravascular volume relative to the individual patient's response to hypovolemia. For patients with a finger thickness of 0.3" to 1" in hospital and pre-hospital settings. CRI trends with changes in intravascular volume relative to the individual patient's response to hypovolemia, and should only be used by qualified medical providers as	The CipherOx CRI Tablet is indicated for continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate (measured by an SpO_2 sensor), and the Compensatory Reserve Index (CRI), which trends changes in intravascular volume relative to the individual patient's response to hypovolemia. For patients with a finger thickness of 0.3" to 1" in hospital and pre-hospital settings. CRI trends with changes in intravascular volume relative to the individual patient's response to hypovolemia, and should only be used by

	an adjunct to rather than as a replacement for traditional hemodynamic measures. CRI is indicated for adults (19-36 years old) in the supine position under non-motion conditions and without cardiovascular disease. CRI has not been studied in trauma patients.	qualified medical providers as an adjunct to rather than as a replacement for traditional hemodynamic measures. CRI is indicated for adults (19-36 years old) in the supine position under non-motion conditions and without cardiovascular disease. CRI has not been studied in trauma patients.
Type of use	Continuous	Continuous
Motion	Non-motion	Non-motion
Patient Population	adults (19-36 years old)	adults (19-36 years old)
Perfusion	Well	Well
Environment of Use	Hospital and prehospital settings	Hospital and prehospital settings
Technology	Transmissive	Transmissive
Batteries	1.5V AAA batteries	3400Wh Lithium Ion Battery
Characteristics		
SpO_2 Display Range	0% to 100% SpO_2	0% to 100% SpO_2
Pulse rate declared accuracy range	18-321 BPM	18-321 BPM
Compensatory Reserve Index	0-1.0 numeric with graph	0-1.0 numeric with graph
Accuracy		
SpO2	± 2 digits	± 2 digits
Pulse rate	18-300 ± 3 digits	20-250 ± 3 digits
Display		
LCD	Daylight readable TFT-color, 2.4”	Multi-pixel 3 digits
Pulse strength indicator	None	None
Data Displayed	SpO_2, pulse rate, CRI, trend (CRI)	SpO_2, pulse rate, CRI, trend (CRI)
Application site	Digits	Digits
Data output	Front panel easy-to-read display (LCD)	Front panel easy-to-read display (LCD)
Operation mode	Continuous	Continuous
LED wavelengths (multiple)	660 and 910 nm	660 and 910 nm
Compensatory Reserve Index		
Hardware	Nonin OEM III internal pulse oximeter module, Nonin 8000AA sensor microcontroller based	Nonin 9560 Pulse Oximeter with integrated sensor Tablet
Software	Flashback CRI algorithm	Flashback CRI algorithm
Physical		
Degree of protection against electric shock	Type BF – applied part	Type BF – applied part
Functional and safety testing	ES 60601-1 IEC 60601-1-2 IEC 60601-1-12 ISO 80601-2-61	ES 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-1-12 ISO 80601-2-61
Biocompatibility	Surface contact Skin Limited duration (<24 hours)	Surface contact Skin Limited duration (<24 hours)

Substantial Equivalence Discussion

Indications –

The CipherOx CRI M1is indicated for continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate (measured by an SpO_2 sensor), and the Compensatory Reserve Index (CRI), which trends changes in intravascular volume relative to the individual patient's response to hypovolemia. For patients with a finger thickness of 0.3" to 1" in hospital and pre-hospital settings.

CRI trends with changes in intravascular volume relative to the individual patient's response to hypovolemia, and should only be used by qualified medical providers as an adjunct to rather than as a replacement for traditional hemodynamic measures. CRI is indicated for adults (19-36 years old) in the supine position under non-motion conditions and without cardiovascular disease. CRI has not been studied in trauma patients.

Patient Population –
The patient population is identical - adults (19-36 years old)

Environment of Use –
The environment of use for use is identical - hospital and pre-hospital settings

Prescriptive –
The "CipherOx CRI M1" and "CipherOx CRI Tablet" are prescriptive.

Design and Technology –
The "CipherOx CRI M1" and "CipherOx CRI Tablet" have equivalent technological and design features. They both calculate SpO_2 and pulse by use of the same technology – the ratio of red and infrared signals of light propagated through the tissue between light sources and detector. Both devices use Photoplethysmography (PPG) signals of red and infrared light through tissue to calculate SpO_2 and pulse rate. Both device use PPG signals to calculate the Compensatory Reserve Index.

Performance Specifications –
The "CipherOx CRI M1" and "CipherOx CRI Tablet" have equivalent specifications.

Compliance with standards –
The "CipherOx CRI M1" complies with AAMI/ANSI/ES60601-1, IEC 60601-1-2, IEC 60601-1-12, and ISO 80601-2-61. The predicate complied with these plus IEC 60601-1-11.

Non-clinical performance testing

Bench -
We have performed bench tests and found that the CipherOx CRI M1 met all requirements specifications and standards requirements and was found to be equivalent in comparison to the predicate. Testing includes the following:

- Verification Testing
- Testing for compliance to AAMI/ANSI/ES 60601-1
- Testing for compliance to IEC 60601-1-2
- Testing for compliance to IEC 60601-1-12
- Testing for compliance to IEC 80601-2-61

The results demonstrate that the devices perform as intended, are substantially equivalent to the performance of the predicate and in accordance with applicable standards.

Biocompatibility / Materials –
The patient contacting materials are part of the Nonin 8000AA sensor. The sensor has been cleared as part of K080255. The Nonin 8000AA sensor used with the CipherOx CRI™ M1 is identical to the cleared device.

Clinical Testing –
The clinical study determining the SpO_2 accuracy for the Nonin OEM III.

Differences –
Differences are primarily related to the predicate "CipherOx CRI Tablet" used a discreet SpO_2 monitor (Nonin 9560) that communicated via wireless to a tablet where compensatory reserve data was calculated and displayed. The tablet also mirrored data from the Nonin 9560. The "CipherOx CRI M1" connects directly to a sensor and contains hardware and software for calculating HR, SpO_2 and compensatory reserve index. The SpO_2 calculations are performed by the Nonin OEM III board. The OEM III board has been demonstrated by UL to function in the CipherOx CRI M1 and has previously been FDA cleared as part of multiple medical devices.

Other differences relate to the battery and range of detected beats per minute which do not alter the function or raise concerns of safety.

We maintain these differences do not raise different questions of safety or effectiveness when compared to the predicate device for the proposed indications for use.

Special Controls
These devices have Special Controls requirements we have reviewed the Special controls which include.

Control	**Evidence**
1. Software description, verification and validation based on comprehensive hazard analysis must be provided including:	
a. Full characterization of technical parameters of the software, including any proprietary algorithm(s);	Software Description
b. Description of the expected impact of all applicable sensor acquisition hardware characteristics on performance and any associated hardware specifications;	Software Description
c. Specification of acceptable incoming sensor data quality control measures;	Software Description
d. Mitigation of impact of user error or failure of any subsystem components (signal detection and analysis, data display, and storage) on accuracy of patient reports;	Software Description

2. Scientific justification for the validity of the status indicator algorithm(s) must be provided. Verification of algorithm calculations and validation testing of the algorithm using a data set separate from the training data must demonstrate the validity of modeling;	The CRI algorithm is identical to that in DEN160020. Critical aspects of hardware such as bandpass, sample rate are identical.
3. Usability assessment must be provided to demonstrate that risk of misinterpretation of the status indicator is appropriately mitigated;	Usability assessment provided.
4. Clinical data must be provided in support of the intended use and include the following:	
a. Output measure(s) must be compared to an acceptable reference method to demonstrate that the output measure(s) represent(s) the predictive measure(s) that the device provides in an accurate and reproducible manner;	The CRI algorithm is identical to that in DEN160020. Critical aspects of hardware such as bandpass, sample rate are identical.
b. The data set must be representative of the intended use population for the device. Any selection criteria or limitations of the samples must be fully described and justified;	The CRI algorithm is identical to that in DEN160020. Critical aspects of hardware such as bandpass, sample rate are identical.
c. Agreement of the measure(s) with the reference measure(s) must be assessed across the full measurement range;	The CRI algorithm is identical to that in DEN160020. Critical aspects of hardware such as bandpass, sample rate are identical.
d. Data must be provided within the clinical validation study or using equivalent datasets to demonstrate the consistency of the output and be representative of the range of data sources and data quality likely to be encountered in the intended use population and relevant use conditions in the intended use environment;	The CRI algorithm is identical to that in DEN160020. Critical aspects of hardware such as bandpass, sample rate are identical.
5. Device labeling must include the following:	
a. The type of sensor data used, including specification of compatible sensors for data acquisition;	User manual includes this warning
b. A description of what the device measures and outputs to the user;	User manual includes this information
c. Warnings identifying sensor reading acquisition factors that may impact measurement results;	User manual includes this information
d. Guidance for interpretation of the measurements, including warning(s) specifying adjunctive use of the measurements;	User manual includes this information
e. Key assumptions made in the calculation and determination of measurements;	User manual includes this information
f. The measurement performance of the device for all presented parameters, with appropriate confidence intervals, and the supporting evidence for this performance; and	User manual includes this information
g. A detailed description of the patients studied in the clinical validation (e.g., age, gender, race/ethnicity, clinical stability) as well as procedural details of the clinical study.	User manual includes this information

Substantial Equivalence Conclusion -
The "CipherOx CRI M1" is substantially equivalent to the predicate in: indications for use, patient population, environment of use, technology characteristics, materials, specifications / performance and compliance with international standards. The differences do not raise different questions of safety or effectiveness when compared to the predicate device for the proposed indications for use.