May 8, 2018

MC10 Inc.
% Jonathan Kahan
Partner
Hogan Lovells
555 13th St. NW
Washington, District of Columbia 20004

Re: K173510
Trade/Device Name: BioStamp nPoint
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter And Receiver
Regulatory Class: Class II
Product Code: DRG, IKN, LEL, MWI
Dated: April 6, 2018
Received: April 6, 2018

Dear Jonathan Kahan:

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

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: January 31, 2017
See PRA Statement on last page

510(k) Number *(if known)*

K173510

Device Name

BioStamp nPoint

Indications for Use *(Describe)*

BioStamp nPoint is a wireless remote monitoring system intended for use by researchers and healthcare professionals for continuous collection of physiological data in home and professional healthcare settings during research studies. These physiological data include heart rate, heart rate variability, respiration rate, activity (including step count and activity classification), and posture (body position relative to gravity). The system is also intended for measurement of surface electromyography, and to monitor limb or body movements during daily living and sleep. Data are transmitted wirelessly from the Sensors for storage and analysis.

The device is intended for use on general care patients who are 18 years of age or older as a general patient monitor, to provide physiological information. The data from the BioStamp nPoint system are only intended for use by researchers and healthcare professionals for research applications, including at the discretion of a qualified healthcare professional as an aid to diagnosis and treatment in the context of clinical research and product development. The device is not intended for use on critical care patients, and is not a real time or remote diagnostic device.

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.

K173510

510(k) SUMMARY

MC10 Inc.'s BioStamp nPoint

Submitter

MC10 Inc.,

10 Maguire Road, Bldg 3, First Floor
Lexington, MA 02421

Phone: 857-214-5600
Facsimile: 781-538-6641

Contact Person: Rakesh Lal, Director of Quality and Regulatory

Strategy Date Prepared: May 4, 2018

Name of Device: BioStamp nPoint

Common or Usual Name: Wireless Remote Monitoring System

Classification Name: Transmitters and Receivers, Physiological Signal, Radiofrequency

Regulation: 21 CFR 870.2910;

Regulatory Class: Class II

Product Code: DRG **Other:** IKN, LEL, MWI

Predicate Devices

Primary predicate: Vital Connect Platform, Healthpatch MD, VitalPatch (K152139)

Subsequent predicate: MotionWatch and PRO-Diary (K132764)

Subsequent predicate: Comprehensive Muscular Activity Profiler Pro (CMAP Pro) (K113074)

Device Description

The BioStamp nPoint system is a wireless remote monitoring platform intended for use by healthcare professionals and researchers for the continuous collection of physiological data in home and healthcare settings. The system is designed only for data collection during research studies.

The BioStamp nPoint system centers on body-worn Wearable Sensor Patches (WSPs) and can be used in both clinic and home settings for up to 24 hours. Study facilitators (either researchers or physicians) set up data collection studies using a web-based study configuration tool, called the Investigator Portal. For supervised uses, the BioStamp nPoint

system includes a Tablet with Investigator Application that study facilitators use to connect to and configure WSPs. When used at home, study subjects interact with the system through the Mobile Phone Link Application. The Link Hub is used to charge and synchronize data from the Wearable Sensor Patches. The BioStamp nPoint system includes an algorithm package that delivers processed metrics on general activity classification, heart rate, heart rate variability, posture, sleep, and respiration during sleep. The BioStamp nPoint system is intended for use on general care patients who are 18 years of age or older and is not intended for use on critical care patients.

The BioStamp nPoint system is comprised of the following components:

System Component	**Description**
Investigator Portal	Website for study facilitators to design supervised and remote studies, enroll subjects, and visualize study data
Investigator Portal (Algorithm Package)	Cloud-based algorithm package to process raw WSP data into algorithm outputs
Wearable Sensor Patches (WSPs)	Wearable Sensor Patches that can be configured to a variety of sensing modalities and worn in various locations on the body
Adhesives	Single-use adhesive stickers for placing WSPs onto the body
Tablet and Investigator App	Tablet based app for study facilitators to initiate data collection. The tablet and app are provided by MC10 and shipped with the system.
Mobile Phone and Sync Application	Smartphone based app for facilitators to upload WSP data in the lab
Mobile Phone and Link Application	Smartphone based app for subjects to receive study instructions, tag activities, input survey entries and control the Wearable Sensor Patches. The phone and app are provided by MC10 and shipped with the system.
Link Hub	Station for charging and transferring data from the WSPs and Mobile Phone Apps

Intended Use / Indications for Use

BioStamp nPoint is a wireless remote monitoring system intended for use by researchers and healthcare professionals for continuous collection of physiological data in home and

professional healthcare settings during research studies. These physiological data include heart rate, heart rate variability, respiration rate, activity (including step count and activity classification), and posture (body position relative to gravity). The system is also intended for measurement of surface electromyography, and to monitor limb or body movements during daily living and sleep. Data are transmitted wirelessly from the Sensors for storage and analysis.

The device is intended for use on general care patients who are 18 years of age or older as a general patient monitor, to provide physiological information. The data from the BioStamp nPoint system are only intended for use by researchers and healthcare professionals for research applications, including at the discretion of a qualified healthcare professional as an aid to diagnosis and treatment in the context of clinical research and product development. The device is not intended for use on critical care patients, and is not a real time or remote diagnostic device.

Summary of Technological Characteristics

A comparison of the technological characteristics of the subject device to the primary predicate, the Vital Connect Platform (K152139), was performed, and it was determined that both devices were largely equivalent to each other in terms of their technological characteristics and methods of operations, and any difference did not raise different questions of safety and effectiveness.

The technological characteristics of the subject device were also compared to the CMAP Pro (K113074) predicate device, and it was determined that both devices were largely equivalent to each other in terms of their technological characteristics related to EMG data gathering, and any difference did not raise different questions of safety and effectiveness.

The technological characteristics of the subject device were also compared to the MotionWatch and PRO-Diary (K132764) predicate device, and it was determined that both devices were largely equivalent to each other in terms of their technological characteristics related to measuring and analyzing physiological motion of the body during daily living and sleep, and any difference did not raise different questions of safety and effectiveness.

Note: The BioStamp nPoint system is not intended to be used for the display of an ECG waveform. The BioStamp nPoint system not intended to be used to detect heart rate in patients with arrhythmia, or ventricular ectopic beats. The respiratory rate function is not intended to provide information to diagnose or treat disease. The respiratory rate function is not for measuring of irregular breathing rhythms.

Performance Data

V&V testing was performed to establish the safety and effectiveness of BioStamp nPoint, and the following performance data has been provided to support the substantial equivalence determination.

Biocompatibility testing included cytotoxicity, irritation, and sensitization according to the recommendations of ISO 10993-1, *Biological evaluation of medical devices – Part 1: Evaluation and testing*.

Safety testing demonstrated the device complies with IEC 60601-1 Edition 3.1, IEC 60601-1-11:2015, IEC 60601-1-6, IEC 62366:2015, IEC 60601-2-40:2016. EMC testing was conducted and demonstrated the device complies with IEC 60601-1-2 Edition 4, and FCC CFR 47 Part 15 Subpart C for wireless communication.

Software V&V testing was performed in accordance with FDA's Guidance for Industry and FDA Staff, *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*. The software contained in the device is determined to be a moderate level of concern, and software V&V testing demonstrated safety and effectiveness of the device.

A human clinical investigation was performed on 30 healthy volunteers to evaluate the performance of the device at measuring heart rate, heart rate variability, respiratory rate, activity (including step count and activity classification), and posture (body position relative to gravity). No adverse events related to the device were encountered, and the results of the clinical investigation demonstrate an effectiveness profile that is similar to the predicate devices.

Conclusions

The BioStamp nPoint has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor differences in indications do not alter the intended diagnostic use of the device and do not affect its safety and effectiveness when used as labeled. In addition, the minor technological differences between the BioStamp nPoint and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the BioStamp nPoint is substantially equivalent to the predicate devices.