October 20, 2022

Collaborative Care Diagnostics LLC, d.b.a. Biomedix
James Hartnett
Quality Manager
860 Blue Gentian Rd
Suite 180
Eagan, Minnesota 55121

Re: K220527
Trade/Device Name: PADnet Xpress
Regulation Number: 21 CFR 870.2780
Regulation Name: Hydraulic, Pneumatic, Or Photoelectric Plethysmographs
Regulatory Class: Class II
Product Code: JOM
Dated: September 20, 2022
Received: September 20, 2022

Dear James Hartnett:

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)*

K220527

Device Name

PADnet Xpress

Indications for Use *(Describe)*

The PADnet Xpress is a non-invasive device used to assess the lower and upper extremity arterial circulatory systems in order to assist in the identification of vascular disease in adults. To assess the arterial system, PADnet Xpress uses pulse volume recording. It is intended to be used by healthcare professionals in either a professional medical or home environment. The device is not intended for pediatric or fetal use. It is also not intended for the use on or near non-intact skin.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Prepared on: 2022-02-23

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Collaborative Care Diagnostics LLC, d.b.a. Biomedix
Applicant Address	860 Blue Gentian Rd Suite 180 Eagan MN 55121 United States
Applicant Contact Telephone	651-280-5570
Applicant Contact	Mr. James Hartnett
Applicant Contact Email	jhartnett@biomedix.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	PADnet Xpress
Common Name	Plethysmographs
Classification Name	Plethysmograph, Photoelectric, Pneumatic Or Hydraulic
Regulation Number	870.2780
Product Code	JOM

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K122281	PADnet 2.0	JOM

Device Description Summary

21 CFR 807.92(a)(4)

PADnet Xpress, like the PADnet 2.0 aids clinicians in the diagnosis of vascular disease by measuring blood volume changes using volume plethysmography in the Brachial, Posterior Tibial, and Anterior Tibial/Dorsalis Pedis arterial distributions. From these signals it calculates a result that is predictive of Peripheral Artery Disease (PAD). Following each test PADnet Xpress provides documented results, including waveforms, as part of the final report, which may be viewed on the system display, in printed form, and/or digitally saved. PADnet Xpress was designed, in response to consumer feedback, to perform a subset of tests, namely PAD screening, which the predicate PADnet 2.0 device is capable of in a smaller, more portable form factor. The design modifications did not alter the intended use and are modest departures from the existing, previously cleared technological characteristics of the predicate, the PADnet 2.0. While the intended use is not altered, there are minor modifications to the indications for use to remove elements of the indication not associated with arterial pulse contour analysis, and segmental systolic & diastolic blood pressure measurements, as well as to allow for home use by a trained operator.

When performing an assessment, the clinician places a sensor and takes a measurement on each upper extremity and each lower extremity. The sensor detects changes in arterial blood volume. This signal is digitized and sent to a computer via a wired connection, where it runs a proprietary software application. The application calculates the result, which is based on the features of the volume plethysmographic signals from the Brachial, Anterior Tibial/Dorsalis Pedis, and Posterior Tibial arterial distributions. The indications for use are almost identical to the PADnet 2.0, the predicate device, but PADnet Xpress has also been tested for compliance with IEC 60601-1-11 home use electrical safety standards and is indicated for use in that environment as well with no change to the safety or effectiveness of the device. The PADnet Xpress sensor, like the sensor used with the predicate, is made from Makrolon plastic.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The PADnet Xpress is a non-invasive device used to assess the lower and upper extremity arterial circulatory systems in order to assist in

the identification of vascular disease in adults. To assess the arterial system, PADnet Xpress uses pulse volume recording. It is intended to be used by healthcare professionals in either a professional medical or home environment. The device is not intended for pediatric or fetal use. It is also not intended for the use on or near non-intact skin.

Indications for Use Comparison 21 CFR 807.92(a)(5)

PADnet Xpress has largely the same indications for use as the predicate device with the only major differences being that the intended environment has been expanded to include home use, and that the device is only capable of performing a subset of the tests of the predicate PADnet 2.0 device. Accordingly, this new device is compliant with IEC 60601-1-11 Home Use electrical safety standards in addition to the IEC 60601-1-1 General Electrical Safety standards for medical devices. The device remains indicated for prescription use only by a medical professional for aiding in the diagnosis of vascular disease. Moving into the home setting does not constitute a new intended use, but instead constitutes an expansion of the current intended use of the predicate device to a new setting, allowing medical professionals to make house calls and screen for vascular disease. Additionally, the removal of the ability to assess the venous system does not constitute a new intended use as it is still able to perform a subset of the tests that the predicate device is indicated for, and a removal of scope does not imply a new use.

Technological Comparison 21 CFR 807.92(a)(6)

PADnet Xpress does not represent a change in technology from the predicate. Instead, it is comprised of only a subset of the technology from the predicate PADnet 2.0 device. The design includes only the sensor from the original device and, as such, has a significantly smaller form factor. The principle of operation is the same as the predicate device and it operates from the same energy source, but the electrical components are simplified to reflect the removal of the pneumoplethysmography functionality. The sensor uses the same material as the sensor on the PADnet 2.0, and the included accessory clip is made from the same material as well.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Since the underlying technology for aiding in the diagnosis of vascular disease is unchanged between the predicate PADnet 2.0 device and the modified PADnet Xpress, a risk analysis determined that additional performance testing was not needed to demonstrate the substantive equivalence of the safety and effectiveness of the device.