April 21, 2023

Atcor Medical PTY Ltd.
Toni Hofhine, President
c/o Sheila Hemeon-Heyer, MS,JD,FRAPS, Consultant
Heyer Regulatory Solutions
125 Cherry Lane
Amherst, MA 01002
USA

Re: K221742
Trade/Device Name: CONNEQT PULSE
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN, DSK
Dated: March 12, 2023
Received: March 13, 2023

Dear Sheila Hemeon-Heyer:

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,

Robert T. Kazmierski -S

for

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.

510(k) Number *(if known)*
K221742

Device Name
CONNEQT PULSE

Indications for Use *(Describe)*
CONNEQT PULSE is a non-invasive blood pressure measurement system that provides a derived ascending aortic blood pressure waveform and a range of central arterial indices. These measurements are provided non-invasively using a technique in which an inflatable cuff is wrapped around the upper arm. Additionally, the CONNEQT PULSE automatically provides brachial systolic and diastolic blood pressures and heart rate. The measurement range of the cuff circumference is 8.6''-12.6''(22cm-32cm) and 12.6''- 16.5''(32cm-42cm).

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.

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510(K) SUMMARY

(In accordance with 21 CFR 807.92)

1.0 Submitter's Information

Name:	ATCOR Medical Pty Ltd.
Address:	301/55 Lime Street Sidney, New South Wales, 2000 Australia
Contact	Toni Hofhine, President
Phone Number:	1-608-354-6712
email	thofhine@atcormedical.com
Date of Preparation:	March 10, 2023

2.0 Device Information

Device Name:	CONNEQT PULSE
Common Name:	Non-Invasive Blood Pressure Measurement System
Classification Name:	Non-Invasive Blood Pressure Measurement System

3.0 Classification

Product Code:	DXN, DSK
Regulation Number:	21 CFR 870.1130, 21CFR870.1110
Classification:	II
Review Panel:	870 Cardiovascular

4.0 Predicate Device Information

	Primary Predicate	Reference Predicate
Manufacturer:	ATCOR Medical Pty Ltd	Andon Health Co. Ltd
Device:	SphygmoCor XCEL	iHealth Wireless Blood Pressure Monitor
510(k) #:	K122129	K162144
Classification	Class II	II
Product Code	DXN, DSK	DXN

5.0 Indications for Use Statement

CONNEQT PULSE is a non-invasive blood pressure measurement system that provides a derived ascending aortic blood pressure waveform and a range of central arterial indices. These measurements are provided non-invasively using a technique in which an inflatable cuff is wrapped around the upper arm. Additionally, the CONNEQT PULSE automatically provides brachial systolic and diastolic blood pressures and heart rate. The measurement range of the cuff circumference is 8.6"-12.6"(22cm-32cm) and 12.6"- 16.5"(32cm-42cm).

6.0 Device Description

The CONNEQT PULSE is designed and manufactured according to IEC 80601-2-30:2019 and consists of the following two parts:

1) Brachial systolic and diastolic blood pressure measurements:
   The operational principle is based on the oscillometric method and silicon integrated pressure sensor technology for determining the brachial systolic and diastolic blood pressure. These blood pressure measurement results are classified for hypertension according to the American Heart Association (AHA) guidelines. The user is also alerted if an irregular heartbeat is detected.
2) Central blood pressure and cardiovascular indices measurement using Pulse Wave Analysis (PWA):
   The central blood pressure measurement and calculation of corresponding central blood pressure parameters are a subset of the central blood pressure parameters provided by the predicate Atcor SphygmoCor XCEL (K122129).

The CONNEQT PULSE can be used on its own or with the optional CONNEQT App on the user's smartphone or CONNEQT PRO App on the healthcare provider's portal. Both Apps are used to transmit patient data from the device using paired Bluetooth Low Energy communication for the purpose of storing and displaying the daily blood pressure data and historical trends. Patient data can also be transmitted from the user's smartphone to their HCP to enable HCP monitoring of the user's cardiac health.

7.0 Comparison of Technological Characteristics with Predicate Device

Primary:

The CONNEQT PULSE is substantially equivalent to the primary predicate device SphygmoCor XCEL as both the proposed and primary predicate devices use an arm cuff to measure and display brachial and central blood pressure. In addition, the central blood pressure parameters that are calculated and displayed by the proposed device are a subset of the central blood pressure parameters that are calculated and displayed by the predicate SphygmoCor XCEL.

Reference:

The technology used for the non-invasive blood pressure (NIBP) measurements by the CONNEQT PULSE, including the arm cuff, device electronics, and the wireless data transmission, is substantially equivalent to the reference predicate device, the iHealth Wireless Blood Pressure Monitor (K162144).

The following table provides a detailed comparison of the subject device to the primary and reference predicate devices,.

Item	Subject Device	Primary Predicate Device (K122129)	Reference Predicate Device (K162144)	Comparison
Trade Name	CONNEQT PULSE	SphygmoCor XCEL	iHealth Wireless Blood Pressure Monitor	--
Model	BPM1AT	XCEL	BPM1	--
Intended Use	CONNEQT PULSE is that provides a derived ascending aortic blood pressure waveform and a range of central arterial indices. These measurements are provided non-invasively using a technique in which an inflatable cuff is wrapped around the upper arm. Additionally, the CONNEQT PULSE automatically provides brachial systolic and diastolic blood pressures. The measurement range of the cuff circumference is 8.6"-12.6" (22cm-32cm) and 12.6"- 16.5" (32cm-42cm).	The SphygmoCor XCEL system provides a derived ascending aortic blood pressure waveform and a range of central arterial indices. These measurements are provided non-invasively through the use of a Brachial cuff. It Is to be used on those patients where information related to ascending aortic blood pressure is desired but the risks of cardiac catheterization procedure or other invasive monitoring may outweigh the benefits. Additionally, the SphygmoCor' XCEL System automatically measures Systolic blood pressure and Diastolic blood pressure. The SphygmoCor XCEL Pulse Wave Velocity (PWV) option is intended to obtain PWV measurements. The PWV option is used on adult patients only.	The BPM1 (Electronic Sphygmomanometer) is intended for use in a professional setting or at home and is a non-invasive blood pressure measurement system. It is designed to measure the systolic and diastolic blood pressures and pulse rate of an adult individual by using a technique in which an inflatable cuff is wrapped around the upper arm. The measurement range of the cuff circumference is 8.6" to18.9" (22cm-48cm).I'	See Note 1
Rx or OTC	Prescription Use (Rx)	Prescription Use (Rx)	OTC	Same as primary predicate device See Note 2
Population	Adult	Adult	Adult	Same

Item	Subject Device	Primary Predicate Device (K122129)	Reference Predicate Device (K162144)	Comparison
Cuff Location	Arm	Arm (for PWA Measurement) Upper thigh (for PWV Measurement)	Arm	See Note 3
Physical Attributes				
Weight (exclude cuff)	About 350g	About 700g	About 350g	Same as reference predicate device
Dimensions	119mm×118mm ×51mm	99mm x 190mm x 172mm	119mm×118mm ×51mm	
Memory	Extended storage on CONNEQT APP 450 readings without CONNEQT APP.	The data of the measurements is not stored in the EM4 device itself, but in an external SQL database installed in the computer that runs the SphygmoCor software.	2×1000 times	See Note 4
Displayed Calculated Parameters	1) Brachial Blood Pressure (SYS/DIA) 2) Heart Rate 3) Central Blood Pressure 4) Central Blood Pressure Parameters (PWA): – Central Pulse Pressure (cPP) – Augmentation Pressure (AP) – Augmentation Index (Alx) – Subendocardial Viability Ratio (SEVR) – Average Central Aortic Pressure Waveform – Central Diastolic – Pressure – Central Mean Arterial Pressure (cMAP)	1) Brachial Blood Pressure (SYS/DIA) 2) Heart Rate 3) Central Blood Pressure 4) Central Blood Pressure parameters (PWA): – Central Pulse Pressure (cPP) – Augmentation Pressure (AP) – Augmentation Index (Alx) – Subendocardial Viability Ratio (SEVR) – Average Central Aortic Pressure Waveform – Central Diastolic – Pressure – Central Mean Arterial Pressure (cMAP)	1) Brachial Blood Pressure (SYS/DIA) 2) Heart ate	Subject device parameters are a subset of those provided by primary predicate device. See Note 5

Item	Subject Device	Primary Predicate Device (K122129)	Reference Predicate Device (K162144)	Comparison
	– Pulse Pressure Amplification (PP Amplification) – Augmentation Index 75 (AIx75)	– Pulse Pressure Amplification (PP Amplification) – Augmentation Index 75 (AIx75) – Ejection Duration – SphygmoCor Reference Age PWV – Measures velocity of pressure pulse between carotid and femoral arterial sites.		
Other Displayed Information	1) Date and Time 2) Battery low indicator 3) Pressure in cuff 4) Blood pressure classification 5) Averages (7 and 30 day measurement averages/trends)	Patient's personal data including Patient ID, Gender, Date of Birth and Age, and Height	Date Time Memory Battery usage Blood pressure classification	See Note 6
Data Transmission	Transmit data to iOS device or Android device with Bluetooth	The SphygmoCor XCEL device is connected to PC using the USB cable	Transmit data to iOS device or Android device via WIFI	See Note 7
Electrical Power				
DC Mains	5V	Input: 100-240 VAC, 50-60Hz Output: 15VDC at 2A	5V	Same as reference predicate device
Battery	1*3.7VLi-ion 2200mAh	N/A	1*3.7VLi-ion 2200mAh	
Environmental Operation				
Temperature	10~40℃	15~40˚C	10~40℃	Same as the reference predicate device
Humidity	≤85%	15% to 95% non-condensing	≤85%	
Environmental Storage				
Temperature	-20~50℃	-20°C to 65°C	-20~50℃	Same as reference predicate device
Humidity	≤85%	20% to 90% non-condensing	≤85%	

Item	Subject Device	Primary Predicate Device (K122129)	Reference Predicate Device (K162144)	Comparison
Performance NIBP/PWA				
Heart Rate Range	40 -180 times/min	30-220 times/min	40 -180 times/min	Same as reference predicate device
Heart Rate Accuracy	Within ±5 beats/min	Within ±5 beats/min	Within ±5%	Same as primary predicate device
Technique/ Method	Oscillometric	Oscillometric	Oscillometric	Same
Measure process	Measure during inflating	Measure during inflating	Measure during inflating	Same
Pressure Accuracy	Within ±3 mmHg	Within ±5 mmHg	Within ±3 mmHg	Same as reference predicate device
Cuff Pressure Range	0-300 mmHg	0-300 mmHg	0 – 300 mmHg	Same
Overpressure Limit	300 mmHg	300 mmHg	300 mmHg	Same
Algorithm	Amplitude (Brachial) PWA Transfer Function (Central)	Amplitude (Brachial) PWA Transfer Function (Central)	Amplitude (Brachial)	Same as primary predicate device
NIBP Pressure Ranges	Sys: 60-260 mmHg Dia: 40-199 mmHg	Sys: 50 - 260 mmHg Dia: 40 – 200 mmHg	Sys: 60-260 mmHg Dia: 40-199 mmHg	Same as reference predicate device
Central blood pressure ranges	40 – 260 mmHg	40 – 260 mmHg	N/A	Same as primary predicate device

DISCUSSION OF DIFFERENCES:

Note #	Difference	Justification
1	Indications for Use	The indications for use statement for the CONNEQT PULSE is substantially equivalent to that of the primary predicate SphygmoCor XCEL. Both the subject and primary predicate devices are used to obtain both brachial and central blood pressure information to enable a HCP to monitor the patient's cardiovascular health. These functions of the subject and primary predicate devices are both derived using pulse-wave analysis (PWA). The accuracy of these parameters for both systems was confimed in clinical testing using the SphygmoCor CvMS as the comparator, which was 5109k) cleared under K070795 and was the predicate device for the SphygmoCor XCEL. The electrical safety report, EMC report, performance testing and clinical testing submitted in this 510(k) confirmed that the subject device is as safe and effective as the primary (K122129) and reference (K162144) predicate devices.
2	Rx or OTC	Both the subject and primary predicate devices are intended for prescription use only. The primary predicate device is intended for use in a professional setting only, while the subject device can be used in a professional or home-use setting. The operation of the subject device is the same as for the reference predicate device, which is sold OTC and is intended for home use. Blood pressure measurement data obtained using the reference predicate device can also be wirelessly transmitted to the user's smartphone. These similarities in operation of the subject device and reference predicate device support the substantial equivalence of the subject device for use as a prescription device in the home setting as well as the professional setting.
3	Cuff Location	The subject device and both the primary and reference predicate devices all use an arm cuff to obtain the blood pressure measurements for pulse wave analysis (PWA). The primary predicate also uses a thigh cuff for pulse wave velocity (PWV) measurements. The subject device does not do PWV and so does not come with a thigh cuff.
4	Memory	The memory for the subject device is different from predicate devices, but the software validation confirmed that the subject device is as safe and effective as the predicate devices.
5	Displayed Calculated Parameters	The displayed calculated parameters for the subject device are a subset of those offered on the primary predicate device. The software validation and clinical testing confirmed that the subject device is as safe and effective as the primary predicate device.

Note #	Difference	Justification
6	Other Displayed Information	The other displayed parameters for the subject device are different from the predicate devices, but the performance testing, clinical testing report and software validation report confirmed that the subject device is as safe and effective as the predicate devices.
7	Data Transmission	Although the method used to transmit data from the subject device to the user's smartphone is via Bluetooth as compared to Wi-fi in the reference predicate device, the electrical safety report, EMC report and software validation report confirmed that the data transmission in the subject device is as safe and effective as the reference predicate device.

8.0 Discussion of Non-Clinical Testing

Non-clinical tests were conducted to verify that the subject device met all of its design specifications. The test results demonstrated that the subject device complies with the following standards:

- IEC 60601-1:2005/(R)2012 And A1:2012, C1:2009/(R)2012 And A2:2010/(R)2012 (Consolidated Text) Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2005, MOD)
- IEC 60601-1-2:2014,Medical Electrical Equipment -- Part 1-2: General Requirements For Basic Safety And Essential Performance -- Collateral Standard: Electromagnetic Disturbances -- Requirements And Tests
- IEC 60601-1-11 Edition 2.0 2015-01 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- IEC 80601-2-30: Edition 2.0 2018-03, Medical Electrical Equipment - Part 2-30: Particular Requirements For The Basic Safety And Essential Performance Of Automated Non-invasive Sphygmomanometers

The software verification and validation were conducted according to IEC 62304:2015. The 510(k) was supported by software documentation appropriate for Moderate level of concern software in compliance with FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", dated May 11, 2005.

All test results were passed and support that the CONNEQT PULSE does not raise new questions of safety and effectiveness compared to the primary and reference predicate devices.

9.0 Clinical Test

Clinical equivalence testing was conducted to verify the accuracies of the brachial and central blood pressure parameters of the CONNEQT PULSE.

1. The accuracies of the brachial systolic and diastolic measurements by the CONNEQT PULSE were validated in accordance with ISO 81060-2:2018, Non-invasive sphygmomanometers - Part 2: Clinical investigation of intermittent automated measurement type. This study included 90 adult subjects (54 female, 36 male) with a mean age of 43 years ± 17 years (range 18 to 75 years). The study test method conformed to the requirements of the ISO 81060-2 standard without deviations, and the test results met the acceptance criteria of the standard and were considered passed.

2. The accuracies of the central blood pressure parameters of the CONNEQT PULSE were validated under an internal protocol that compared the CONNEQT PULSE to the SphygmoCor CvMS (K070795) device using the same test method as was previously used to validate the predicate SphygmoCor XCEL device (K122129) in comparison to the SphygmoCor CvMS. Forty-one subjects (20 female/21 male, mean age 44 ± 19 years, range 20 to 85 years) distributed equally between three age groups: <30 years (N=13, 6 female/7 male); 30 to 60 years (N=17, 10 female/7 male); above 60 years (N=11, 4 female/7 male) participated in the investigation. Statistical tests were conducted to measure the equivalence between the results of the CONNEQT PULSE device and the 510(k) cleared comparator device. The test results demonstrated high agreement between the central blood pressure parameters generated by the CONNEQT PULSE and the SphygmoCor CvMS, which was also previously shown to have high agreement with the predicate SphygomoCor XCEL, thus confirming substantial equivalence.

10. Comparison to the Predicate Devices and Conclusion

The conclusion drawn from the nonclinical clinical testing demonstrate that the CONNEQT PULSE is substantially equivalent to the primary predicate SphygmoCor XCEL device in its indications for use and performance in measuring brachial and central blood pressure and calculating central blood pressure parameters. In addition, the technology and operation of the CONNEQT PULSE is the same as the reference predicate iHealth Wireless Blood Pressure device. Therefore, the subject device is substantially equivalent to the legally marketed predicate devices (K122129 and K162144).