510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of SMDA and 21 CFR 807.92.

1.0 submitter information

Name: Andon Health Co., Ltd.

Address: No.3 Jinping Street, Ya An Road, Nankai District, Tianjin, P.R. China

Phone number: 86-22-87611660

Fax number: 86-22-6052 6162

Contact: Yi Liu

Date of Preparation: 6/6/2018

2.0 Device information

Trade name: Connect App for iHealth Next

Common name: Data management software

Classification name: Data management software

3.0 Classification

Production code: DXN, MNW, DQA
Regulation number: 21 CFR 870.2770, 21 CFR 870.1130, 21 CFR 870.2700,
Classification: II
Panel: 870 Cardiovascular

4.0 Predicate device information

Manufacturer: Andon Health Co., Ltd.

Device: Apps-Health01

510(k) number: K122098

5.0 Device description

The Connect App for iHealth Next is a software for using it with health devices,

including iHealth medical devices such as Blood Pressure Monitor and pulse oximeter, etc. It can also be used with non-medical devices, such as active monitor, weight scale, etc.

The Connect App for iHealth Next can:
(1) Connect to blood pressure monitor and control the meter to complete measurement, and the data can be transferred to the Connect App for iHealth Next;
(2) Connect to pulse oximeter and transfer data from the pulse oximeter to the Connect App for iHealth Next.

Below is detailed control information:

Device type	**Model (510K number)**	**Control description**	**Control way**	**Electrical safety and EMC test evidence**	
Blood pressure monitor	KD-936 (K120672)	a*	b**	c*	d*
	KD-972 (K121470)	a*	b**	c*	d*
	BP3L (K152003)	a*	b*	c*	d*
	KN-550BT (K160014)	a**	b*	c*	d*
	BP7S (K152379)	a**	b*	c*	d*
Pulse oximeter	PO3M (K131111)	a**	b*	c*	d*
Control description: a* the App can control medical devices to start/stop the measurement and receive data from blood pressure monitor. a** the App only receives data from medical devices					
b* the medical device can only be controlled by App b** the medical device can be controlled both by medical device and by App					
Electrical safety test performed in the previous 510Ks c* Electrical safety test according to IEC 60601-1:2005+C1:2006,					
EMC test performed in the previous 510Ks d* EMC test according to IEC 60601-1-2:2007					

6.0 Intended use

The Connect App for iHealth Next is intended for use in home settings as an aid for people to view vital signs which are measured by iHealth devices (non-invasive blood pressure monitor and pulse oximeter).

The Connect App for iHealth Next should not be used to either self-diagnose a disease state or exclude it. Please consult your physician if you find the reading is above a normal threshold.

7.0 Summary comparing technological characteristics with predicate device

Specification Comparison table

	Predicate device	**Proposed device**
Device name	Apps-Health01	Connect App for iHealth Next
Product type	software	software
Indications for use	The Apps-Health01 is intended for use in home settings as an aid for people to review, analyze, and evaluate test results which are measured from a blood pressure monitor or scale.	The Connect App for iHealth Next App is intended for use in home settings as an aid for people to view vital signs which are measured by iHealth devices.
Software platform	iOS	iOS and Android
Hardware requirements	iPhone, iTouch, iPad	iPhone, iTouch, iPad, mobile device with Android system
Measurement control	Measurement module with Native SDK as transfer module	Measurement module
Function-basic	Blood pressure: Test or manually input blood pressure data. Weight: Test or manually input body composition data.	Connect to blood pressure: complete measurement and transfer test data Connect to pulse oximeter and transfer test data

Function-other	My calorie Trends: View your calories consumed vs. calories burned. Reminders: Set reminders (Medicine/Measure blood pressure /Measure weight/Sport) to stay focused on your goals. My plan: Add and modify your weight goals. My BP trends: View your blood pressure trends. My weight Trends: View your weight data. History: view of your historical data. My Diary: Log food and activities to stay on track.	Check FAQ
Meter Compatibility	Scales, Blood Pressure Monitor	Blood Pressure Monitor, Pulse Oximeter, Weight scale Active monitor
Connection with peripheral device by	Bluetooth （HS5 with WIFI additionally, KD-931 by apple 30PIN）	Bluetooth Bluetooth Low Energy Audio
Performance test provided	Software validation	Software validation

8.0 Performance summary

Non-clinical test

Software validation

Software validation has been performed according to FDA guidance "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". And the result conforms that the proposed device is as safe and effective as the predicate device.

Usability study

Usability test has been performed according to FDA guidance "Apply for applying human factors and usability engineering to medical devices".

20 lay users and 20 professionals participated in this study on their actual use environment such as home, hospital, clinic and office etc.,

in order to verify that:

- ✓ user can choose the device correctly,
- ✓ user can operate the device in proper environment as intended,
- ✓ user can get all the warning and precaution as intended,
- ✓ user can download and run the app correctly, and
- ✓ user can operate the device correctly,

The following main critical tasks were identified in this study,

- ✧ Read App operation guide and medical device labeling
- ✧ Download and run the App
- ✧ Connect medical device to App
- ✧ Complete measurement

The study results demonstrate that the Connect App for iHealth Next are understood by a variety of users, and provide sufficient information for the safe and effective use of the device.

Wireless Coexistence test

Wireless coexistence test has been performed to verify that the proposed device can be used in intended environments.

Clinical test

This section is not applicable.

9.0 Comparison to the predicate device and the conclusion

The Connect App for iHealth Next is similar with the predicate device Apps-Health01. The new device can be used with more medical devices such as the pulse oximeter. Additionally, the proposed device can also be installed in Android mobile devices.

The tests and data in this submission demonstrate that the proposed device is as safe and effective as the predicate device.