March 8, 2018

Shanghai Hulu Devices Co., Ltd.
% Dave Yungvirt
Third Party Review Group, LLC
The Old Station House
24 Lackawanna Place
Millburn, New Jersey 07041

Re: K180335
    Trade/Device Name: Accutension Smartphone Auscultatory Blood Pressure Kit
    Regulation Number: 21 CFR 870.1120
    Regulation Name: Blood Pressure Cuff
    Regulatory Class: Class II
    Product Code: DXQ, DQD
    Dated: February 5, 2018
    Received: February 6, 2018

Dear Dave Yungvirt:

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
Indications for Use

Accutension Smartphone Auscultatory Blood Pressure Kit is intended for professionals or home users to nonautomatically measure systolic and diastolic blood pressure on adults by detecting Korotkoff sounds and measure pulse rate on adults by detecting oscillometry. This device is not indicated for children, heart failure patients and critical patients.

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
PRASstaff@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

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

Submitted by: Shanghai Hulu Devices Co., Ltd
No. 509 Caobao Road, Room 101-2 Bld 9, Xuhui District, Shanghai, China

Contact Person: Junfeng Zhao
Phone: 0086-18621892190
Fax: 0086-21-56782078#805
Email: zhaoap@hotmail.com

Date Prepared: Mar 26, 2017
Device Name: Accutension Smartphone Auscultatory Blood Pressure Kit
Model: XYZ-110
Common Name: Blood Pressure Cuff
Classification: II
Regulation Number: 870.1120
Regulation Name: Blood Pressure Cuff
Product Code: DXQ, DQD

5.1 Predicate Device
Aneroid Sphygmomanometer BK2002 (Wenzhou Bokang Instrument Co., Ltd, K043286) is used as a predicate device compared to Accutension Smartphone Auscultatory Blood Pressure Kit on blood pressure measurement.

HEM-7320 (OMRON HEALTHCARE, INC., K133383) is used as a predicate device compared to Accutension Smartphone Auscultatory Blood Pressure Kit on pulse rate measurement.

5.2 Reference Device
AliveCor Heart Monitor (AliveCor, Inc., K142743) is used as a reference device compared to Accutension Smartphone Auscultatory Blood Pressure Kit on store and record waveforms.

5.3 Device Description
The Accutension Smartphone Auscultatory Blood Pressure Kit (Model XYZ-110) is a non-invasive blood pressure measurement system for professionals and home users to nonautomatically measure systolic and diastolic blood pressure and pulse rate. It utilizes advanced pressure sensing module to transfer cuff pressure value to an iOS App via established Bluetooth connection between the module and the iOS device during measurement, meanwhile a stethoscope detects Korotkoff sounds and transfers the sound signal to the smartphone via its earphone jack. Both the cuff
pressure and auscultatory sounds are visualized in the app and a user can determine
the systolic and diastolic blood pressure by finding the cuff pressures on the first and
last Korotkoff sounds. It automatically calculates the pulse rate based on cuff
pressure oscillometry.

This device consists of 5 parts, arm cuff, pressure sensing module, hand pump (bulb)
with airflow valve, stethoscope with earphone plug and charging cable. None of the 5
parts of the Accutension Smartphone Auscultatory Blood Pressure Kit have received
510(k) clearance on their own as a stand-alone device. Instead, collectively, they are
considered to be components of a device that is substantially equivalent to the cited
predicate device.

5.4 Indication for Use
Accutension Smartphone Auscultatory Blood Pressure Kit is intended for
professionals or home users to nonautoamatically measure systolic and diastolic
blood pressure on adults by detecting Korotkoff sounds and measure pulse rate on
adults by detecting oscillometry. This device is not indicated for children, heart failure
patients and critical patients.

The indication for use statement is similar to that of the predicate device K043286 on
blood pressure measurement: The device is intended to be used by medical
professional or in the home for the measurement of systolic and diastolic pressure on
adults. The device is intended to be manually attached to patient and manually
inflated along with a manual method for detecting Korotkoff sounds. In both
statements, the user who operate the device is the same: either professionals or
home users, the subject who is measured is the same: adults, the function is the
same: measure systolic and diastolic blood pressure, and the method is the same:
detecting Korotkoff sounds. The proposed device emphasizes that it is not for
children, heart failure patients and critical patients to further clarify the
measurement subjects.

The indication for use statement is similar to that of the predicate device K133383 on
pulse rate measurement. The pulse rate measurement method is the same. Both use
oscillometry to calculate the pulse rate.

5.5 Technology Characteristics
Accutension Smartphone Auscultatory Blood Pressure Kit uses the Korotkoff sounds
based blood pressure determination method that is used by the predicate device.
Here is a comparison on the technology characteristics between the current device
and the predicate device.

<table>
<thead>
<tr>
<th>Technology Characteristics</th>
<th>Current Device</th>
<th>Predicate Device</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cuff design</td>
<td>Fabric cuff</td>
<td>Fabric cuff</td>
<td>Same</td>
</tr>
<tr>
<td>with bladder</td>
<td>with bladder</td>
<td>Same</td>
<td></td>
</tr>
<tr>
<td>--------------</td>
<td>-------------</td>
<td>------</td>
<td></td>
</tr>
<tr>
<td>Cuff inflation mechanism</td>
<td>Manual inflation with hand pump</td>
<td>Manual inflation with hand pump</td>
<td>These two types of pressure sensor has the same grade of accuracy defined in ISO 81060-1.</td>
</tr>
<tr>
<td>Cuff pressure gauge</td>
<td>Electrical pressure sensor</td>
<td>Mechanical pressure sensor</td>
<td>The pressure displayed on the smartphone is digitalized (directly show the cuff pressure number). The predicate device uses a needle to point to the cuff pressure number in the dial. These two are similar because a user can get the cuff pressure number in either way.</td>
</tr>
<tr>
<td>Pressure display</td>
<td>Displayed on a smartphone</td>
<td>Displayed on a mechanical dial</td>
<td></td>
</tr>
<tr>
<td>Korotkoff sounds picking</td>
<td>Stethoscope head</td>
<td>Stethoscope head</td>
<td>The mechanical mechanism of the stethoscope head is similar</td>
</tr>
<tr>
<td>Korotkoff sounds processing</td>
<td>Recorded with a microphone sensing the picked Korotkoff sounds from the stethoscope head and then playback to the human ear.</td>
<td>The sounds directly go to the human ear.</td>
<td>The difference is that the current device records the sounds first and then playback the sounds to the human ears for blood pressure determination while the predicate device transfer the sounds directly to the human ears for blood pressure determination.</td>
</tr>
<tr>
<td>Blood pressure determination</td>
<td>By listening to the Korotkoff sounds with human ear</td>
<td>By listening to the Korotkoff sounds with human ear</td>
<td>The same</td>
</tr>
<tr>
<td>Sounds and cuff pressure visualization</td>
<td>Sounds and cuff pressure are visualized</td>
<td>No such feature</td>
<td>This provides an extra feature to help capture the first and last Korotkoff sounds for blood pressure determination.</td>
</tr>
<tr>
<td>Blood pressure storage</td>
<td>The blood pressure readings can be stored in</td>
<td>No such feature</td>
<td>This provides an extra feature to track blood pressure history.</td>
</tr>
</tbody>
</table>
Overall, the current device uses more up-to-date technologies to implement the same blood pressure measurement method used by the predicate device to improve blood pressure measurement.

### 5.6 Applicable Guidance Document


### 5.7 Clinical Test

255 pairs of data from 85 valid subjects were achieved following the clinical study protocol defined in ISO 81060-2:2013. Same arm simultaneous method was adopted during the clinical validation for Accutension Smartphone Auscultatory Blood Pressure Kit. A manual Mercury Sphygmomanometer was used as a reference device in the clinical testing. All the subjects who enrolled in this study were well informed of the value and the risk of the study by the researchers and signed the consent forms before they took part in the clinical study. The results showed the accuracy of the device made by Shanghai Hulu Devices Co, Ltd. satisfies the criteria specified in ISO 81060-2:2013.

### 5.8 Non-clinical Test

#### 5.8.1 Biocompatibility Testing


<table>
<thead>
<tr>
<th>Biocompatibility Test</th>
<th>Standard requirement</th>
<th>Test Result</th>
<th>Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>In Vitro Cytotoxicity Test</td>
<td>ISO 10993-5:2009 Cytotoxicity</td>
<td>The test article did not show potential toxicity to L-929 cells.</td>
<td>Qualified</td>
</tr>
<tr>
<td></td>
<td>Should no toxicity.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Guinea Pig Maximization Test</td>
<td>ISO 10993-10:2010</td>
<td>No significant evidence of causing skin sensitization in the guinea pig.</td>
<td>Qualified</td>
</tr>
<tr>
<td></td>
<td>There should be no skin sensitization</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Skin Irritation Test</td>
<td>ISO</td>
<td>The response of</td>
<td>Qualified</td>
</tr>
</tbody>
</table>
5.8.2 Performance Testing
We have performed bench tests and found that the Accutension Smartphone Auscultatory Blood Pressure Kit met all requirements specifications and standards requirement. Testing includes the following:
- Testing for compliance to IEC 60601-1:2012
- Testing for compliance to IEC 60601-1-2:2014
- Testing for compliance to IEC 60601-1-11:2015
- Testing for compliance to ISO 81060-1:2007
- Testing for compliance to FCC CFR Title 47 Part 15 Subpart C Section 15.247
Besides the testing for compliance, we did the additional bench tests:
- Testing to demonstrate pulse rate accuracy
- Testing to demonstrate wireless co-existence
- Testing to demonstrate stethoscope performance

5.8.2.1 Usability Study Summary
30 people participated in human factor validation testing, in which 15 participants are general users while another 15 participants are healthcare professionals, to simulate the use of the device in both home and clinical office environment. All the participants completed all the tasks without use error. The results showed the Accutension Smartphone Auscultatory Blood Pressure (BP) Kit is safe and effective for the intended users, uses and use environments.

5.8.2.2 Synchronization Testing Summary
Synchronization of the stethoscope sounds and cuff pressures was tested. In the test, the same stethoscope sounds and cuff pressures collected by the Accutension Smartphone Auscultatory Blood Pressure Kit were compared with those directly sensed by a data acquisition card. The later one has a zero time difference in theory. The time difference criteria was set as $-150\text{ms} < \Delta T < 150\text{ms}$. The measured $\Delta T_{\text{max}}$ is less than 150ms and passed the test.

5.9 Conclusion
The biocompatibility testing results demonstrate the equivalence to the predicate device on biocompatibility requirement. The performance testing results demonstrate the same level of safety, effectiveness and performance though new technology characteristics are introduced. The clinical test results demonstrate the current device is as safe and effective (accurate) in a clinical environment. In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, based on
the information provided in this premarket notification, Shanghai Hulu Devices Co., Ltd concludes that Model XYZ-110 Accutension Smartphone Auscultatory Blood Pressure Kit is substantially equivalent to the predicate and complies to testing defined in ISO 81060-1 standard.

5.10 Others
Shanghai Hulu Devices Co., Ltd will update and include in this summary any other information deemed necessary by FDA.