DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 21, 2014

LG Electronics
c/o Ms. Diane Sudduth
Senior Consultant, RA/Q/A
816 Congress Avenue, Suite 1400
Austin, TX 78701

Re: K133997
Trade/Device Name: LG SmartHealth
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency physiological signal transmitter and receiver
Regulatory Class: Class II
Product Code: DRG
Dated: November 19, 2014
Received: November 20, 2014

Dear Ms. Sudduth:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Melissa A. Torres -S

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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K133997

Device Name
LG SmartHealth

Indications for Use *(Describe)*
The LG SmartHealth is intended to collect vital sign measurements from physiological measurement devices intended for use in the home . Patients can review the stored vital sign measurement information and receive educational and motivational content from caregivers(or nurse). Patients can also engage in video conferences with caregivers(or nurse).

The LG SmartHealth is not interpretive, nor is it intended for diagnosis or as a substitute for medical care, and it is not intended to provide real time data. It is made available to patients when time-critical care is not required.

The LG SmartHealth is contraindicated for patients requiring direct-medical supervision or emergency intervention. It is intended for patients who are willing and capable of managing its use. Clinical judgment and experience by a caregiver are required to check and interpret the information delivered.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

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"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

for

LG SmartHealth

1. Submission Sponsor

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Contact: Dr. Diane Sudduth, Senior Consultant, QA
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3. Date Prepared

December 21, 2013

4. Device Identification

Trade/Proprietary Name:	LG SmartHealth
Common/Usual Name:	Remote Patient Monitoring System
Classification Name:	Transmitters and Receivers, Physiological Signal, Radiofrequency
Classification Regulation:	870.2910
Product Code:	Product Code DRG
Device Class:	Class II
Classification Panel:	Cardiovascular

5. Legally Marketed Predicate Device(s)

Intel Health Guide Express (K103276)

6. Device Description

The LG SmartHealth application is software planned to operate on the Android operating system (OS) that can be loaded as an application or "app" on a commercially available smartphone. LG intended the software to work on the Android OS, as well as to operate on smartphones as well. The scalability and differences between many smartphones today are not too great to allow this flexibility and option.

The LG SmartHealth application connects to commercially available wireless medical devices that are commonly used by patients in a home-care setting. These "sensor devices" are FDA cleared or FDA registered (Exempt) devices that can communicate with the LG SmartHealth application software loaded on the smartphone using Bluetooth connectivity. To avoid wireless interference and confusion on the part of the patient, serial readings are performed (i.e. only one Bluetooth sensor used at a time) and MAC address filtering is used for the various medical devices. The LG SmartHealth application plans to support the following sensor available medical devices, some initially, and others as the technology becomes available:

- Glucose meters or glucometers
- Blood pressure cuffs
- Weight scales
- Body fat readers
- Activity monitors

On each screen of the LG SmartHealth application software a help button is present, which when pressed provides step-by-step based help to guide a patient through an interaction.

The medical device takes a reading depending on the frequency previously established and the LG SmartHealth application software fetches the information for the reading automatically. The LG SmartHealth application software stores and displays the information on the smartphone and transmits the information to the server. The LG SmartHealth application encrypts the information in preparation for transmit using SHA256 bit encryption, complying with HIPAA requirements.

7. Indication for Use Statement

The LG SmartHealth is intended to collect vital sign measurements from physiological measurement devices intended for use in the home. Patients can review the stored vital sign measurement information and receive educational and motivational content from caregivers (or nurse). Patients can also engage in video conferences with caregivers (or nurse).

The LG SmartHealth is not interpretive, nor is it intended for diagnosis or as a substitute for medical care, and it is not intended to provide real time data. It is made available to patients when time-critical care is not required.

The LG SmartHealth is contraindicated for patients requiring direct-medical supervision or emergency intervention. It is intended for patients who are willing and capable of managing

its use. Clinical judgment and experience by a caregiver are required to check and interpret the information delivered.

8. Substantial Equivalence Discussion

The comparison chart below provides evidence to facilitate the substantial equivalence determination between LG SmartHealth to the predicate device (K103276) with respect to intended use, technological characteristics and principles of operation.

Table 5A – Comparison of Characteristics

Features and Specifications	**Intel® Health Guide Express** ***(K103276)***	**LG SmartHealth** (Subject Device)
Regulatory Information		
Intended Use/ Indications for Use	The Intel® Health Guide Express is intended to collect vital sign measurements from physiological measurement devices intended for use in the home. Patients can review the stored vital sign measurement information and receive educational and motivational content from caregivers. Patients can also engage in video conferences with caregivers and answer the caregivers' questions by participating in surveys. The Intel® Health Care Management Suite allows the caregiver to review patient data and initiate video conferencing with patients, or select and send educational and motivational content to patients. The Intel® Health Guide Express is not interpretive, nor is it intended for diagnosis or as a substitute for medical care, and it is not intended to provide real time data. It is made available to patients when time-critical care is not required. The Intel® Health Guide Express is contraindicated for patients requiring direct-medical supervision or emergency intervention. It is intended for patients who are willing and capable of managing its use. Clinical judgment and experience by a caregiver are required to check and interpret the information delivered.	The LG SmartHealth is intended to collect vital sign measurements from physiological measurement devices intended for use in the home. Patients can review the stored vital sign measurement information and receive educational and motivational content from caregivers (or nurse). Patients can also engage in video conferences with caregivers (or nurse). The LG SmartHealth is not interpretive, nor is it intended for diagnosis or as a substitute for medical care, and it is not intended to provide real time data. It is made available to patients when time-critical care is not required. The LG SmartHealth is contraindicated for patients requiring direct-medical supervision or emergency intervention. It is intended for patients who are willing and capable of managing its use. Clinical judgment and experience by a caregiver are required to check and interpret the information delivered.
OTC and/or Rx	Rx	Same

User Characteristics		
Intended User	Patient in Home Setting	Same
Device		
• **Components**	• Web based software application • Data Transfer Tool (Integrated)	• Smart phone app based software application • Data Transfer Tool (Integrated)
User Interface Device	Computer Device (i.e. desktop, laptop)	Android Device(i.e. Smart phone, tablet)
Connectivity to Device	Bluetooth or USB wired	Bluetooth
Ability to Update Device Settings	Not available	Automatic deploy
Connectivity to Web-based Services	Login Secured by SSL Encryption	Same
Operating System	Microsoft Windows 7 (32-bit versions)	Android 2.3.3 or higher
Supported Device Types	Medical devices designed for home use: Blood glucose meter Weight scale Blood pressure Pulse Oximeter FEV/PEF	Medical devices designed for home use: Blood glucose meter Weight scale Blood pressure Temperature Activity Monitor
Software Delivery	Web download for the uploader only	Same
Software Features		
Patient Management	Manage patient accounts, filter/sort/search patients, print reports.	The server connected to the mobile device manages patient accounts, filter/sort/search patients
Implementation method of collecting data from sensors	Bluetooth or USB wired	Bluetooth
Communication frequency	Bluetooth: 2.402 to 2.480 GHz	Same
Max data throughput under worst case conditions	Multiply read data can be stored in the medical device and they are resent to the server after recovery of network condition	Same

Use of thresholds/algorithms for determining how thresholds are set and changed	Thresholds set by healthcare professional in server software	Same
Communication method with server	Connected through internet	Same

The LG SmartHealth is a medical device and has similar indications for use statement as the predicate device. The differences in the indications statement between LG SmartHealth and Intel Health Guide Express do not alter the intended use – both devices have essentially the same intended use.

The device also has similar technological characteristics as the predicate device. Both devices have the same data collection software functionality, communication method of patient device with central server, types of sensors which can be interfaced to the patient device, implementation method of collecting data from sensors, sensor software, connectivity, and communication protocol. Since the comparison of the descriptive characteristics of the proposed and predicate devices may not be sufficiently precise to assure equivalence, performance data are provided. The results of the performance testing demonstrate substantial equivalence.

9. Non-Clinical Performance Data

The device's software development, verification, and validation have been carried out in accordance with FDA guidelines. The software was tested against the established Software Design Specifications for each of the test plans to assure the device performs as intended. The device Hazard analysis was completed and risk control implemented to mitigate identified hazards. The testing results support that all the software specifications have met the acceptance criteria of each module and interaction of processes. The LG SmartHealth device passed all testing and supports the claims of substantial equivalence and safe operation.

Validation activities included a usability study of the LG SmartHealth under actual use. The study demonstrated:

- Comprehension of the study nurses and participants with the LG SmartHealth,
- Appropriate human factors related to the LG SmartHealth, and
- Ease of use of the LG SmartHealth.

10. Clinical Performance Data

There was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. These types of devices, including the predicate devices, have been on the market for many years with a proven safety and efficacy for the use of the device. The verification and validation testing of the device's software was found to be acceptable and supports the claims of substantial equivalence.

11. Statement of Substantial Equivalence

The LG SmartHealth has the same or similar intended use as the predicate device and that any technological differences between the LG SmartHealth software and the predicate device do not raise any questions regarding LG SmartHealth ('SmartHealth')'s safety and effectiveness.

The information provided in this submission supports the substantial equivalence to the predicate device and that the system is safe and effective for the users/operators.