U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER:	(kml)
FOLDER:	K133997 - 965 pages
COMPANY:	LG ELECTRONICS (LGELECB)
PRODUCT:	TRANSMITTERS AND RECEIVERS, PHYSIOLOGICAL SIGNAL, RADIOFREQUENCY (DRG)
SUMMARY:	Product: LG SMARTHEALTH
DATE REQUESTED:	Dec 20, 2015
DATE PRINTED:	Dec 20, 2015
Note:	Printed

EMERGO GROUP

K133997/A001

January 8, 2014

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Cardiac Diagnostics Devices Branch,
Division of Cardiovascular Devices
10903 New Hampshire Avenue
W066-1244
Silver Spring, Maryland 20993-0002

FDA/CDRH/DCC
JAN 10 2014
RECEIVED

Dear Oscar;

LG Electronics ('LG'), LG SmartHealth, hereby submits this response to the agency's request for information **K133997** email dated January 8, 2014. The purpose of this submission is to address the deficiencies identified during FDA's review of the 510(k) submission.

In regard your comments that the submission contains both, prescription and OTC designation, the OTC check box on the Indications for Use FDA Form was inadvertently selected. This submission is for prescription use only, and is evidenced by the Rx indications in the 510(k) Summary, Executive Summary, User Manual (pg. 4) and Section 12 – Substantial Equivalence table. A revised Indications for Use FDA Form 3881 will be provided as an **Exhibit A**.

As both the predicate and the LG SmartHealth device are indicated for prescription use only, we believe the analysis of the differences between the LG SmartHealth and the predicate is appropriate. It should be noted that the comparison table correctly indicated Rx status for both the predicate and the LG SmartHealth devices and referenced in the 510(k) Summary, Executive Summary, and Section 12 – Substantial Equivalence document.

Per your comment regarding labeling, the User Manual correctly indicated the prescription use statement on page 3 of 39, 026_Exhibit 13A – UHCTX-MNL 01 v1 0h.pdf. The name and place of business of the manufacturer is provided within the User Manual (Exhibit 13A) in section 1.8, page 4 of 39.

The CD provided with the submission is the official electronic copy of the submission; the eCopy is an exact duplicate of the paper copy.

We appreciate your prompt consideration of this submission. If you have any questions, please contact me at 561.305.5075 or by email at project.management@emergogroup.com.

Sincerely,

Diane Sudduth

Diane Sudduth
Senior Consultant, RA/QA

EMERGO GROUP

January 8, 2014

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Cardiac Diagnostics Devices Branch,
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10903 New Hampshire Avenue
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We appreciate your prompt consideration of this submission. If you have any questions, please contact me at 561.305.5075 or by email at project.management@emergogroup.com.

Sincerely,

Diane Sudduth

Diane Sudduth
Senior Consultant, RA/QA

5006-0710

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)*

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.

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."

EMERGO GROUP

K133997

Section 3 – 510(k) Cover Letter

FDA CDRH DMC
DEC 27 2013
Received

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Dear Sir or Madam:

This document contains the information for LG Electronics, LG SmartHealth submission for market clearance. In accordance with Section 510(k) of the Federal Food and Drug Cosmetic Act as amended, and in conformance with Title 21 CFR, Part 807, this Pre-market Notification is being submitted at least ninety (90) days prior to the date when LG Electronics proposes to introduce its LG SmartHealth into interstate commerce for commercial distribution. The CD provided with the submission is the official electronic copy of the submission; the eCopy is an exact duplicate of the paper copy. Following contains the regulatory information for the contents of this submission supporting the device's market clearance.

Administrative Information

Date of Submission:	December 26, 2013
Submission is Completed By:	Emergo Group 816 Congress Avenue Suite 1400 Austin, TX 78701
Application Correspondent:	Dr. Diane Sudduth Senior Consultant QA, Emergo Group Email: project.management@emergogroup.com Cellphone number: 561.305.5075 Home office number: 512.327.9997
Submission Sponsor: LG Electronics	38 Baumoe-ro, Seocho-gu Seoul, 137-724 Korea Chang Hee Lee Chief Research Engineer Office number: +82-2-526-4370

Device Identification

Type of 510(k) Submission:	Traditional
Trade or Proprietary Name:	LG SmartHealth
Common or Usual Name:	Remote Patient Monitoring System
Regulation Classification:	Transmitters and Receivers, Physiological Signal, Radiofrequency

EMERGO GROUP INC. 816 Congress Ave| Suite 1400 | Austin, Texas 78701 | USA | Telephone: +1 512 327 9997

5006-1212

Product Code:	870.2910 (Product Code DRG)
Class of Device:	Class II
Panel:	Cardiovascular
Reason for Submission:	New device
Prior Related Submissions:	No prior submissions for the device

Design and Use of the Device

Table 3A – Principle Factors

Question	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?		X
Is the device intended for single use?		X
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		N/A
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?	X	
Does the submission include clinical information?		X
Is the device implanted?		X

All information necessary for a substantial equivalence determination is included herein. Should you require any additional data in order to reach a determination of substantial equivalence, please do not hesitate to contact me at 561.305.5075 or by email at project.management@emergogroup.com

Sincerely,

Diane Sudduth

Diane Sudduth
Senior Consultant, RA/QA

EMERGO GROUP INC. 816 Congress Ave| Suite 1400 | Austin, Texas 78701 | USA | Telephone: +1 512 327 9997

5006-1212

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Section 6 Truth and Accuracy Statement
Section 7 Class III Summary and Certification
Section 8 Financial Certification or Disclosure Statement
Section 9 Declaration of Conformity and Summary Reports
Section 10 Executive Summary
Section 11 Device Description
Section 12 Substantial Equivalence Discussion
Section 13 Proposed Labeling
Section 14 Sterilization and Shelf Life – **Not Applicable**
Section 15 Biocompatibility – **Not Applicable**
Section 16 Software
Section 17 Electromagnetic Compatibility and Electrical Safety – **Not Applicable**
Section 18 Performance Testing – Bench – **Not Applicable**
Section 19 Performance Testing – Animal – **Not Applicable**
Section 20 Performance Testing – Clinical
Section 21 Exhibits (Other)

LIST OF SECTIONS

		Present	Not Applicable
Section 1	**Medical Device User Fee Cover Sheet (FDA Form 3601)**	X	
Section 2	**CDRH Premarket Review Cover Sheet (FDA Form 3514)**	X	
Section 3	**510(k) Cover Letter**	X	
	Administrative Information		
	Device Identification		
	Design and Use of the Device		
	Table 3A – Principle Factors		
Section 4	**Indications for Use Statement**	X	
Section 5	**510(k) Summary**	X	
	Submission Sponsor		
	Submission Correspondent		
	Device Identification		
	Predicate Devices		
	Device Description		
	Intended Use		
	Comparison of Technological Characteristics		
	Table 5A – Comparison of Characteristics		
	Non-Clinical Performance Data		
	Clinical Testing		
	Statement of Substantial Equivalence		
Section 6	**Truth and Accuracy Statement**	X	
Section 7	**Class III Summary and Certification**		X
Section 8	**Financial Certification or Disclosure Statement**		X
Section 9	**Declaration of Conformity and Summary Reports**	X	
	Risk Management Declaration of Conformity		
	Software Design and Development Declaration of Conformity		
	Table 9A – List of Voluntary Standards		
Section 10	**Executive Summary**	X	
	Summary of Device		
	Indications for Use		
	Device Comparison Summary		
	Table 10A – Device Comparison Table		
	Performance Testing Summary		
Section 11	**Device Description**	X	
	Description of the Device		
Section 12	**Substantial Equivalence Discussion**	X	
	Comparison to Legally Marketed Device		
	Table 12A – Device Comparison Chart: Similarities and Differences		
	Performance Testing Summary		
	Table 12B – Performance Summary		
	Comparison Discussion		
Section 13	**Proposed Labeling**	X	

		Present	Not Applicable
	Labeling Table 13A – Labeling Information		
Section 14	**Sterilization and Shelf Life**		X
Section 15	**Biocompatibility**		X
Section 16	**Software**	X	
	Device Description Level of Concern Table 16A – Major Level of Concern Rationale Table 16B – Moderate Level of Concern Rationale Level of Concern for OTS Software Table 16C – Summary of Software Documentation Software Description Figure 1 – SmartHealth Operating Structure Figure 2 – Televisit Process Figure 3 – Medication Management Process Figure 4 – Remote Patient Monitoring Process Software Development Table 16D – Process Outputs, Tools, Methodology and Technology Table 16E – Standard Reference List of Outputs Table 16F - Infrastructure Figure 5 – Software Development Process Software Requirements Specification Architecture Design Chart Figure 6 – External Interface Specification Figure 7 – Password Encryption Algorithm Figure 8 – LG SmartHealth Architecture Layer Software Design Specification Device Hazard Analysis Traceability Analysis Verification and Validation Documentation Revision Level History Unresolved Anomalies Software Certification		
Section 17	**Electromagnetic Compatibility and Electrical Safety**		X
Section 18	**Performance Testing – Bench**		X
Section 19	**Performance Testing – Animal**		X
Section 20	**Performance Testing – Clinical**	X	
Section 21	**Intentionally left blank**		
EXHIBITS			
Exhibit 6A	Signed Truth and Accuracy Statement	X	
Exhibit 9A	Standards Data Report IEC 62304 2006/C11 2008 (Form FDA 3654)	X	
Exhibit 9B	Standards Data Report ISO 14971 2007 (Form FDA 3654)	X	

		Present	Not Applicable
Exhibit 12A	510(k) Summary for Intel Health Guide PHS6000 (K103276)	X	
Exhibit 13A	LG Electronics User Manual	X	
Exhibit 16A-1	Software Requirements Specifications (common)	X	
Exhibit 16A-2	Software Requirements Specifications (Telemedicine)	X	
Exhibit 16A-3	Software Requirements Specifications (Measurement)	X	
Exhibit 16A-4	Software Requirements Specifications (Medication)	X	
Exhibit 16B	Software Architecture Document	X	
Exhibit 16C-1	High Level Design Document (common)	X	
Exhibit 16C-2	High Level Design Document (Telemedicine)	X	
Exhibit 16C-3	High Level Design Document (Measurement)	X	
Exhibit 16C-4	High Level Design Document (Medication)	X	
Exhibit 16D	Requirements Traceability Matrix	X	
Exhibit 16E	Risk Management File	X	
Exhibit 16F	Integration/System Test Plan	X	
Exhibit 16F-1	Integration/System Test Protocol (common)	X	
Exhibit 16F-2	Integration/System Test Protocol (Telemedicine)	X	
Exhibit 16F-3	Integration/System Test Protocol (Measurement)	X	
Exhibit 16F-4	Integration/System Test Protocol (Medication)	X	
Exhibit 16G	Verification Test Report	X	
Exhibit 16H	Validation Test Report	X	
Exhibit 16H	Software Certificate	X	
Exhibit 18A	Bluetooth Communication Test Report	X	
Exhibit 20A	Signed Certificate of Compliance for Clinical Trials (Form FDA 3674)	X	

Section 1 - Medical Device User Fee Cover Sheet (FDA Form 3601)

Device Name: LG SmartHealth

The FDA Form 3601 Medical Device User Fee Sheet is contained in this section.

Form Approved OMB No. 0910-0511 Expiration Date April 30, 2016. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b) (4) [redacted]
Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

LG ELECTRONICS INC INCHEON FACTORY
816 Congress Avenue
Suite 1400
Austin
TX 78701
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)

2. CONTACT NAME
Melissa Brightwell

2.1 E-MAIL ADDRESS
mbrightwell@emergogroup.com

2.2 TELEPHONE NUMBER (include Area code)
512-222-0256

2.3 FACSIMILE (FAX) NUMBER (Include Area code)

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm

Select an application type:

[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] 30-Day Notice

3.1 Select a center

[X] CDRH
[ ] CBER

3.2 Select one of the types below

[X] Original Application

Supplement Types:

[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA

[X] NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?

[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)

[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates

[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only

[ ] The sole purpose of the application is to support conditions of use for a pediatric population

[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).

[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT
Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for

reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850
[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b) (4) [redacted] 26-Dec-2013

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

Online Payment

Step 3: Confirm Payment

1 | 2 | 3

Thank you.
Your transaction has been successfully completed.

Pay.gov Tracking Information

Application Name: (b) (4) [redacted]
Pay.gov Tracking ID: b [redacted]
Agency Tracking ID: b [redacted]
Transaction Date and Time: b [redacted]

Payment Summary

Address Information	Account Information	Payment Information
Account Holder Name: (b) (4) [redacted]	Card Type: ([redacted]	Payment Amount: (b) (4) [redacted]
Billing Address: (b) (4) [redacted] b(4)Tr [redacted]	Card Number: (b) (4) [redacted]	Transaction Date and Time: (b) (4) [redacted] b(4) [redacted]
Billing Address 2: b(4)Trade [redacted]		
City: b(4)T [redacted]		
State / Province: b([redacted]		
Zip / Postal Code: b(4)T [redacted]		
Country: b(4) [redacted]		

Section 2 – CDRH Premarket Review Submission Cover Sheet (FDA Form 3514)

Device Name: LG SmartHealth

The CDRH Premarket Review Submission Cover Sheet is contained in this section. Standard Data Report Forms (FDA Forms 3654) for applicable standards are referenced in Section 9 Declaration of Conformity and Summary Reports of this submission.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 9010-0120
Expiration Date: August 31, 2010.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number (if known)
12/26/2013	(b)(4)	

SECTION A — TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA &HDE Supplement			☐ Other *(specify)*:
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission)*:
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☒ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B — SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name LG Electronics	Establishment Registration Number *(if known)*		
Division Name *(if applicable)* N/A	Phone Number *(including area code)* ( ) +82-2-526-4370		
Street Address 38 Baumoe-ro, Seocho-gu	FAX Number *(including area code)* ( )		
City Seoul	State / Province	ZIP/Postal Code	Country Korea
Contact Name Chang Hee Lee			
Contact Title Chief Research Engineer	Contact E-mail Address chp.lee@lge.com		

SECTION C — APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name Emergo Group			
Division Name *(if applicable)*	Phone Number *(including area code)* (512) 327-9997		
Street Address 816 Congress Avenue, Suite 1400	FAX Number *(including area code)* (512) 327-9998		
City Austin	State / Province TX	ZIP/Postal Code 78701	Country USA
Contact Name Diane Sudduth			
Contact Title Senior Regulatory Consultant	Contact E-mail Address project management@emergogroup.com		

SECTION D1 — REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Process change:
  - ☐ Manufacturing
  - ☐ Sterilization
  - ☐ Packaging
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Response to FDA correspondence:

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify)*:

SECTION D2 — REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Repose to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify)*:

SECTION D3 — REASON FOR SUBMISSION - 510(k)

- ☒ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

- ☐ Other Reason *(specify)*:

SECTION E — ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	DRG	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- [x] 510 (k) summary attached
- [ ] 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K103276	1	Intel Health Guide PHS6000	1	INTEL CORPORATION DIGITAL HEALTH GROUP
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F — PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

Remote Patient Monitorng System

	Trade or Proprietary or Model Name for This Device		Model Number
1	LG SmartHealth	1	TBD
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1 N/A	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

- [ ] Laboratory Testing
- [ ] Animal Trials
- [ ] Human Trials

SECTION G — PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code
DRG

C.F.R. Section *(if applicable)*
870.2910

Classification Panel
Cardiovascular

Device Class

- [ ] Class I
- [x] Class II
- [ ] Class III
- [ ] Unclassified

Indications *(from labeling)*

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.

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number TBD	☒ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler		
Company / Institution Name LG Electronics		Establishment Registration Number TBD		
Division Name *(if applicable)* N/A		Phone Number *(including area code)* ( ) +82-2-526-4370		
Street Address 38 Baumoe-ro, Seocho-gu		FAX Number *(including area code)* ( )		
City Seoul		State / Province	ZIP/Postal Code	Country Korea
Contact Name Chang Hee Lee	Contact Title Chief Research Engineer		Contact E-mail Address chl@lge.com	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler		
Company / Institution Name		Establishment Registration Number		
Division Name *(if applicable)*		Phone Number *(including area code)* ( )		
Street Address		FAX Number *(including area code)* ( )		
City		State / Province	ZIP/Postal Code	Country
Contact Name	Contact Title		Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler		
Company / Institution Name		Establishment Registration Number		
Division Name *(if applicable)*		Phone Number *(including area code)* ( )		
Street Address		FAX Number *(including area code)* ( )		
City		State / Province	ZIP/Postal Code	Country
Contact Name	Contact Title		Contact E-mail Address	

SECTION I	UTILIZATION OF STANDARDS				
Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.					
1	Standards No. IEC 62304	Standards Organization International Electrotechnical Commission (IEC)	Standards Title Medical device software - software life cycle processes. (Software/Informatics)	Version 2006	Date 8/20/2012
2	Standards No. ISO 14971	Standards Organization International Standards Organization	Standards Title Medical devices - Application for risk management to medical devices	Version 2007	Date 3/1/2007
3	Standards No.	Standards Organization	Standards Title	Version	Date
4	Standards No.	Standards Organization	Standards Title	Version	Date
5	Standards No.	Standards Organization	Standards Title	Version	Date
6	Standards No.	Standards Organization	Standards Title	Version	Date
7	Standards No.	Standards Organization	Standards Title	Version	Date

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
CDRH (HFZ-342)
9200 Corporate Blvd.
Rockville, MD 20850

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Section 3 – 510(k) Cover Letter

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Dear Sir or Madam:

This document contains the information for LG Electronics, LG SmartHealth submission for market clearance. In accordance with Section 510(k) of the Federal Food and Drug Cosmetic Act as amended, and in conformance with Title 21 CFR, Part 807, this Pre-market Notification is being submitted at least ninety (90) days prior to the date when LG Electronics proposes to introduce its LG SmartHealth into interstate commerce for commercial distribution. The CD provided with the submission is the official electronic copy of the submission; the eCopy is an exact duplicate of the paper copy. Following contains the regulatory information for the contents of this submission supporting the device's market clearance.

Administrative Information

Date of Submission:	December 26, 2013
Submission is Completed By:	Emergo Group 816 Congress Avenue Suite 1400 Austin, TX 78701
Application Correspondent:	Dr. Diane Sudduth Senior Consultant QA, Emergo Group Email: project.management@emergogroup.com Cellphone number: 561.305.5075 Home office number: 512.327.9997
Submission Sponsor: LG Electronics	38 Baumoe-ro, Seocho-gu Seoul, 137-724 Korea Chang Hee Lee Chief Research Engineer Office number: +82-2-526-4370

Device Identification

Type of 510(k) Submission:	Traditional
Trade or Proprietary Name:	LG SmartHealth
Common or Usual Name:	Remote Patient Monitoring System
Regulation Classification:	Transmitters and Receivers, Physiological Signal, Radiofrequency

Product Code:	870.2910 (Product Code DRG)
Class of Device:	Class II
Panel:	Cardiovascular
Reason for Submission:	New device
Prior Related Submissions:	No prior submissions for the device

Design and Use of the Device

Table 3A – Principle Factors

Question	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?		X
Is the device intended for single use?		X
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		N/A
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?	X	
Does the submission include clinical information?		X
Is the device implanted?		X

All information necessary for a substantial equivalence determination is included herein. Should you require any additional data in order to reach a determination of substantial equivalence, please do not hesitate to contact me at 561.305.5075 or by email at project.management@emergogroup.com

Sincerely,

Diane Sudduth

Diane Sudduth
Senior Consultant, RA/QA

EMERGO GROUP INC. 816 Congress Ave | Suite 1400 | Austin, Texas 78701 | USA | Telephone: +1 512 327 9997

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)*

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.

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
for
LG SmartHealth

1. Submission Sponsor

LG Electronics
38 Baumoe-ro, Seocho-gu
Seoul, 137-724
Korea
Phone: +82-2-526-4527
Fax: +82-2-526-4370
Contact: Chang Hee Lee, Chief Research Engineer

2. Submission Correspondent

Emergo Group
816 Congress Avenue, Suite 1400
Austin, TX 78701
Cell Phone: (561) 305-5075
Office Phone: (512) 327.9997
Fax: (512) 327.9998
Contact: Dr. Diane Sudduth, Senior Consultant, QA
Email: project.management@emergogroup.com

3. Date Prepared

December 26, 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 Patient Monitoring System 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 Patient Monitoring system 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 Patient Monitoring system 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 Patient Monitoring system 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 Patient Monitoring 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 Patient Monitoring software fetches the information for the reading automatically. The LG Patient Monitoring software stores and displays the information on the smartphone and transmits the information to the server. The LG Patient Monitoring system 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.

Section 6 – Truthful and Accurate Statement

Device Name: LG SmartHealth

As required by 21 CFR 807.87(k), the Truthful and Accurate Statement on company letterhead by a responsible person at LG Electronics is attached in Exhibit 6A.

Section 7 - Class III Certification and Summary

Device Name: LG SmartHealth

Conclusion: Not applicable; Class II device

Section 8 – Financial Certification or Disclosure Statement

Device Name: LG SmartHealth

Conclusion: Not applicable as clinical trials were not performed with the device.

Section 9 - Declarations of Conformity and Summary Reports

Device Name: LG SmartHealth

The submission is a Traditional 510(k) Submission with no device-specific guidance documents or any declaration of conformity to recognized standards specified by the device regulation. No specific performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act. However, certain voluntary standards and guidance have been used in the design and testing of this device.

Risk Management Declaration of Conformity:

- ISO 14971: 2007, Medical devices -- Application of risk management to medical devices

For the voluntary standards listed above, LG Electronics certifies that the results from the requisite testing performed meet specified acceptance criteria and the LG SmartHealth software conforms to applicable and relevant portions of each respective standard.

Software Design and Development Declaration of Conformity:

The LG SmartHealth software complies with the applicable voluntary standards that include IEC 62304:2006/C11:2008 for Medical Device Software – Software Lifecycle processes and FDA General Principles of Software Validation; Final Guidance for Industry and FDA Staff, dated January 11, 2002. The Software Verification and Validation Summary reports are included in Section 16 – Software section of the submission.

- IEC 62304:2006/C11:2008 – Medical Device Software – Software Lifecycle processes

The Standard Data Report, FDA Form-3654 is attached as Exhibit 9-A and Exhibit 9-B in order to provide more detailed conformance information for the recognized voluntary standards.

Table 9-A – List of Voluntary Standards

Standard	FDA Recognition Number	Exhibit
IEC 62304:2006/C11:2008	13-32	Exhibit 9-A
ISO 14971:2007	5-40	Exhibit 9-B

Section 10 – Executive Summary

Device Name: LG SmartHealth

Summary of Device:

The LG Patient Monitoring System 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 Patient Monitoring system 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 Patient Monitoring system 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 Patient Monitoring system 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 Patient Monitoring 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 Patient Monitoring software fetches the information for the reading automatically. The LG Patient Monitoring software stores and displays the information on the smartphone and transmits the information to the server. The LG Patient Monitoring system encrypts the information in preparation for transmit using SHA256 bit encryption, complying with HIPAA requirements.

Indications for Use:

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.

Device Comparison Summary:

Table 10A – Device Comparison Table

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 wired USB	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

Performance Testing Summary:

The LG Integration/System Test Plan, included in Section 16, Exhibit 16-F of this submission, describes the approach used for verification and validation of the LG SmartHealth Application. Full verification and validation testing of the LG SmartHealth software was performed in accordance with the FDA Guidance Document 'General Principles of Software Validation (2002)'. System Level Integration testing were conducted based on the requirements identified in the LG Software Requirements Documents (Exhibits 16-A through Exhibit 16-G), included in Section 16 of this 510(k) Submission.

A risk based approach to the software integrity level is followed to determine the level of verification that will be performed on each module and includes:

- Ad-hoc Testing
- Formal Testing
- Code Reviews
- System Level Integration Testing

Each module underwent System Level Integration Testing and/or Code Review.

For a summary and details of the verification and validation conducted on the LG SmartHealth, please refer to Section 16 of this 510(k) submission.

Section 11 – Device Description

Device Name: LG SmartHealth

Description of the Device:

The LG Patient Monitoring System Software ("LG SmartHealth") 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 Electronics 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.

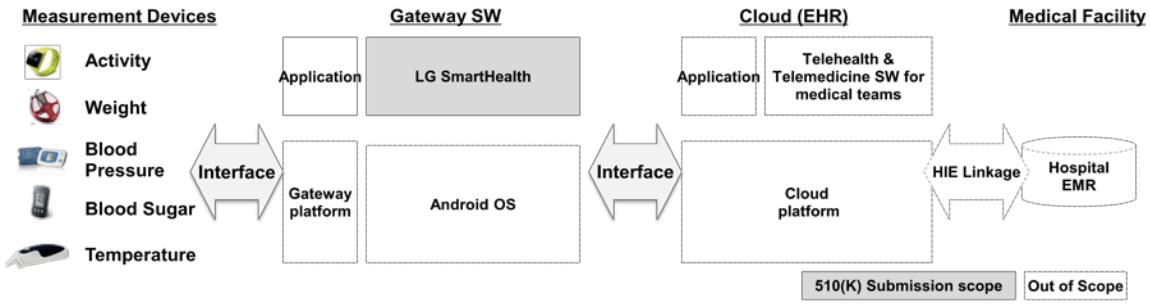

Figure 1 LG SmartHealth Operation Structure

LG SmartHealth 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 SmarthHealth loaded on the smartphone 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. LG SmartHealth plans to support the following sensor available medical devices, some initially, and then others as the technology become available:

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

Pressing the measurement guide button in LG SmartHealth provides a step-by-step interactive help guide to the user.

The medical device takes a reading depending on the frequency previously established and the LG Patient Monitoring software fetches the information for the reading automatically. The LG Patient Monitoring software stores and displays the information on the smartphone and transmits the information to the server. The LG Patient Monitoring System encrypts the password using SHA256 algorithm b(4)Trade Secret Process-Product Specs [redacted] complying with HIPAA requirements.

These medical devices that are sensor, monitoring, and recording devices will all be FDA cleared or FDA Class I, 510(k) Exempt products that are recommended by LG for use with their Patient Monitoring System. A list of the acceptable medical devices that can be used with the LG Patient Monitoring System will be provided in the User's Manual.

Device Type	Vendor	Model	Connection	k number
Blood pressure monitor	A&D Medical	UA-767PBT	Bluetooth wireless device	K043217
	FORA	P 20 Blood Pressure Monitor lU-RIGHT TD-3 132 Blood Pressure Monitor	Bluetooth wireless device	K092106
	FORA	D30F: Fora Comfort 2 in 1 blood glucose plus blood pressure monitoring system	Bluetooth wireless device	K080014
Glucose monitor	Bayer HealthCare	Contour	Wired device	K121190
	LifeScan, a Johnson & Johnson Company	OneTouch Ultra Mini	USB wired device	K061118
	CareSens	CareSens **N** LINK Blood Glucose Monitoring System	Bluetooth wireless device	K130696
Weight scale	Biospace	IH-U070B H20	Bluetooth wireless device	K123228
	Tanita Corp. of America	BC590 BT	Bluetooth wireless device	K014009
Temperature Meters	Fora	IR20b TypeI/II	Bluetooth wireless device	K090395
Activity Tracker	LG	Life Gram	Bluetooth Wireless device	Exempt

Naming Convention:

Please note that LG SmartHealth may also be referred to as "SmartHealth", "SmartHealth app", or "LG SmartHealth" in many of the attached documents.

Indications 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.

Mode of Operation and Mechanism of Action:

(b) (4)

[redacted]

(b) (4)

[redacted]

Proposed Conditions of Use:

Software & Hardware Requirement

(b)(4) Software

[redacted]

Labeling:

The LG SmartHealth is a Smartphone app based software application which will be accessible via a URL address. The user manual will be provided in a downloadable PDF format which can be viewed, saved, or printed. The user manual provides instructions on how to access and operate the software.

Section 12 – Substantial Equivalence Discussion

Device Name: LG SmartHealth

The LG SmartHealth is equivalent to the Intel Health Guide Express, cleared in K103276, on 8 February 2011.

The LG SmartHealth is equivalent to the predicate in terms of data collection software functionality, operating system for the patient device, 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, communication protocol and display method.

A copy of the 510(k) summary for the Intel Health Guide Express is included in Exhibit 12-A as the predicate device for this submission.

Comparison to Legally Marketed Device:

Table 1 on the following page provides a comparison between the subject system and the predicate device.

Table 12A – Device Comparison Chart: Similarities and Differences

Features	LG SmartHealth (Pending)	Intel® Health Guide Express (K103276)	Significant Difference
Regulatory Information			
Intended Use	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.	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.	Similar; LG SmartHealth's Indications Statement is a subset of Intel Health Guide Express in that the predicate extends the indications to allow the caregiver to review patient data and initiate video conferencing, or select and send educational and motivational content to patients.

Features	LG SmartHealth (Pending)	Intel® Health Guide Express (K103276)	Significant Difference
OTC and/or Rx	Rx	Rx	No significant difference
User Characteristics			
Intended User	Patient in Home Setting	Patient in Home Setting	No significant difference
Device			
Components	• Smartphone app based software application • Data Transfer Tool (Integrated)	• Web based software application • Data Transfer Tool (Integrated)	LG SmartHealth is an Andriod based app
User Interface Device	Android Device(i.e. Smart phone)	Computer Device (i.e. desktop, laptop)	Both of them are off the shelf devices
Connectivity to Device	Bluetooth Interface	Bluetooth Interface or wired USB	LG SmartHealth is a subset of Intel Health Guide Express
Ability to Update Device Settings	Automatic deploy	Automatic deploy	No significant difference
Connectivity to Web-based Services	Login Secured by SSL Encryption	Login Secured by SSL Encryption	No significant difference
Operating System	Android 2.3.3 or higher	Microsoft Windows 7 (32-bit versions)	LG Smartphone operates on different operating system

Features	LG SmartHealth (Pending)	Intel® Health Guide Express (K103276)	Significant Difference
Supported Device Types	Medical devices designed for home use: • Blood Glucose Meters • Blood Pressure • Weight • Temperature • Activity tracker(N/A)	Medical devices designed for home use: • Blood Glucose Level • Blood Pressure • Weight • Oxygen Saturation • FEV/PEF	LG SmartHealth supports a subset of the predicate BGM, blood pressure devices
Software Delivery	Web download for the uploader only	Web download for the uploader only	No significant difference
Software Features			
Patient Management	Manages patient accounts, filter/sort/search patients, print reports	Manage patient accounts, filter/sort/search patients, print reports.	No significant difference

The comparison chart above provides evidence to facilitate the substantial equivalence determination between LG SmartHealth and our chosen predicate, Intel Health Guide Express.

There is a direct correlation between the Indications for Use Statement/Intended Use of LG SmartHealth and Intel Health Guide Express. Both devices are software applications used 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. They both have the same connectivity to devices, ability to update device settings, connectivity to web-based services, and software delivery.

The difference in the Indications Statement between LG SmartHealth and Intel Health Guide Express is that the Intel® Health Care Management Suite extends the use to allow for the caregiver to review patient data and initiate video conferencing with patients, or select and send educational and motivational content to patients. Both devices add a specific requirement that it should not be used as 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. Additionally, both LG SmartHealth and Intel Health Guide Express are 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 technological characteristics between the LG SmartHealth and Intel Health Guide Express are different, as the software operates on different hardware. Although both devices support blood glucose meters, blood pressure monitors and weight scales, the Intel Health Guide Express provides additional functionality in regard to compatibility to oximeters and FEV/PEF sensors. LG SmartHealth does not provide these functionalities. These differences are addressed through labeling and the compatibility with medical devices are evidenced by the results of the Performance testing.

All these facts provide evidence to facilitate the substantial equivalence determination between LG Smartphone and the predicate device, Intel Health Guide Express (K103276).

Performance Testing Summary:

Internal verification and validation testing confirms that product specifications are met which are equivalent in design and technological characteristics as the predicate device. The testing results support that the functional testing met for the acceptance of the device. The LG SmartHealth passed all testing and supports the claims of substantial equivalence to the predicate device.

Table 12B – Performance Summary

Information or Testing Summarized	Section Located
Proposed Labeling of Device	Section 13
Software	Section 16

Conclusions:

In conclusion, LG Electronics believes that we have established substantial equivalence of the subject LG SmartHealth to the predicate. No new issues of safety or effectiveness are introduced by using this device. The basis for our conclusion is reached through successful review of product design specifications and testing results compared to the predicate device. This consideration included review of the requirements for substantial equivalence delineated in the June 30, 1986, Center for Devices and Radiological Health (CDRH) publication entitled *Guidance on the Center for Devices and Radiological health's Premarket Notification Review Program*, which includes a flow chart entitled 510(k) Substantial Equivalence Decision Making Process (Detailed).

Section 13 – Proposed Labeling

Device Name: LG SmartHealth

Labeling:

The LG SmartHealth is a Smartphone app based software application which will be accessible via a URL address. The user manual will be provided in a downloadable PDF format which can be viewed, saved, or printed. The user manual provides instructions on how to access and operate the software.

Copies of the following draft labeling which describes the device in detail and provides user instructions is provided in Exhibit 13A.

Promotional labeling for the LG SmartHealth has not yet been developed. Claims for this device will be consistent with the draft user manual and currently marketed substantially equivalent devices (descriptions and labeling provided later in the "Substantial Equivalence" section of this notification).

Section 14 – Sterilization and Shelf Life

Device Name: LG SmartHealth

Conclusion: This is not applicable to software products.

Section 15 – Biocompatibility

Device Name: LG SmartHealth

Conclusion: This section is not applicable to software products.

Section 16 – Software Description

Device Name: LG SmartHealth

Device Description:

The LG Patient Monitoring System Software ("LG SmartHealth") 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 Electronics 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.

LG SmartHealth 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 SmarthHealth loaded on the smartphone 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. LG SmartHealth plans to support the following sensor available medical devices, some initially, and then others as the technology become available:

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

When measurement guide button in LG SmartHealth 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 Patient Monitoring software fetches the information for the reading automatically. The LG Patient Monitoring software stores and displays the information on the smartphone and transmits the information to the server. The LG Patient Monitoring System encrypts the password using SHA256 algorithm (b) (4) [redacted], complying with HIPAA requirements.

These medical devices that are sensor, monitoring, and recording devices will all be FDA cleared or FDA Class I, 510(k) Exempt products that are recommended by LG for use with their Patient Monitoring System. A list of the acceptable medical devices that can be used with the LG Patient Monitoring System will be provided in the User's Manual.

16.1 Level of Concern:

Based on the Risk Management File (Exhibit 16-E) and the FDA Guidance document, *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*, issued on May 11, 2005, on levels of concern LG has determined that the software level of concern for the LG SmartHealth device is **Moderate**. The rationale for the decision on the software level of concern is shown below in the tables extracted from the Food and Drug Administration guidance document.

Table 16-A – Major Level of Concern Rationale

If the answer to any one question below is Yes, the Level of Concern for the Software Device is likely to be Major.		
Question	**Answer**	**Rationale**
1. Does the Software Device qualify as Blood Establishment Computer Software?	NO	The device is not a Blood Establishment Computer Software.
2. Is the Software Device intended to be used in combination with a drug or biologic?	NO	The device is not intended to be used in conjunction with a drug or biologic.
3. Is the Software Device an accessory to a medical device that has a Major Level of Concern?	NO	The device is not an accessory to a medical device that has a major level of concern.
4. Prior to mitigation of hazards, could a failure of the Software Device result in death or serious injury, either to a patient or to a user of the device? Examples of this include the following:		
a. Does the Software Device control a life supporting or life sustaining function?	NO	The device does not control a life sustaining or life supporting function.
b. Does the Software Device control the delivery of potentially harmful energy that could result in death or serious injury, such as radiation treatment systems, defibrillators, and ablation generators?	NO	The software does not control the delivery of potentially harmful energy that could result in a death or serious injury.
c. Does the Software Device control the delivery of treatment or therapy such that an error or malfunction could result in death or serious injury?	NO	The device does not control the delivery of treatment or therapy such that an error or malfunction could result in death or serious injury.
d. Does the Software Device provide diagnostic information that directly drives a decision regarding treatment or therapy, such that if misapplied it could result in serious injury or death?	NO	The software device processes (displays) digital information for the assessment of treatment only. This information does not directly mandate or control a decision regarding treatment or therapy as all digital information must be interpreted by a competent medical person together with any additional clinical information required for treatment.
e. Does the Software Device provide vital signs monitoring and alarms for potentially life threatening situations in which medical intervention is necessary?	NO	The device does not provide any vital signs monitoring and/or alarms.

Table 16-B – Moderate Level of Concern Rationale

If the answer to any one question below is Yes, the Level of Concern for the Software Device is likely to be Moderate.		
Question	**Answer**	**Rationale**
1. Is the Software Device an accessory to a medical device that has a Moderate Level of Concern?	YES	The device is not an accessory to a medical device that has a major level of concern.
2. Prior to mitigation of hazards, could a failure of the Software Device result in Minor Injury, either to a patient or to a user of the device?	NO	A failure of the software device would not result in Minor Injury, either to a patient or to a user of the device if mitigation of hazards were not implemented.
3. Could a malfunction of, or a latent design flaw in, the Software Device lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury?	YES	A malfunction or a latent design flaw in the software device could lead to an erroneous diagnosis that would lead to a minor injury.

(b)(4) Software

[redacted]

(b)(4) Software

[redacted]

16.2 Software Description:

(b)(4) Software

[redacted]

(b)(4) Software

[redacted]

(b)(4) Software

[redacted]

16.3 Software Development:

(b)(4) Software

[redacted]

(b)(4) Software

[redacted]

(b)(4) Software

[redacted]

(b)(4) Software

[redacted]

16.4 Software Requirements Specification:

(b)(4) Software

[redacted]

(b)(4) Software

[redacted]

(b)(4) Software

[redacted]

(b)(4) Software

[redacted]

(b)(4) Software

[redacted]

16.6 Software Design Specification:

b(4)Trade Secret Process-Software Specs

[redacted]

16.7 Device Hazard Analysis:

(b) (4)

[redacted]

(b)(4) Testing

[redacted]

(b)(4) Testing

[redacted]

(b)(4) Testing

[redacted]

(b)(4) Testing

[redacted]

(b)(4) Testing

[redacted]

(b)(4) Testing

[redacted]

(b)(4) Testing

[redacted]

(b)(4) Testing

[redacted]

(b)(4) Testing

[redacted]

Section 17 – Electromagnetic Compatibility and Electrical Safety

Device Name: LG SmartHealth

Conclusion: This section is not applicable to software products.

Section 18 – Performance Testing - Bench

Device Name: LG SmartHealth

The evaluation of data transmission for connection and accuracy was completed during verification testing. The requirement for BT pairing connection time, linkage recognition, and measurement data accuracy is according to the Software Requirements Specification (SRS) submitted in Exhibit 16A-1 thru 16A-4 of this submission. A protocol was followed to test all device connection requirements including verifying that the results are transferred to LG SmartHealth on Android Device without distortion.

The result of this protocol was 100% Pass for all three (3) meters, three (3) BP monitors, three (3) weight scales, two (2) temperature monitors, and one (1) activity tracker. See Exhibit 18A, section 5 for results of all device connection and data accuracy requirements.

Conclusion: For LG SmartHealth software version 1.2.8, all test cases passed. There were no test failures. LG SmartHealth software version 1.2.8 is considered acceptable for use.

Section 19 – Performance Testing - Animal

Device Name: LG SmartHealth

Conclusion: This section is not applicable to software products.

Section 20 – Performance Testing - Clinical

Device Name: LG SmartHealth

Not applicable. Clinical testing is not necessary to demonstrate substantial equivalence of this device as there are no new innovative aspects that have been introduced. These types of software programs and applications have been on the market for several years with no significant incidents of safety or efficacy for the predicate devices. The design, development and testing of the LG SmartHealth has not resulted in the need for any clinical trials.

The Food and Drug Administration Form 3674 Certificate of Compliance for Clinical Trials is attached to the submission as Exhibit 20A.

LG Electronics
38, Baumoe-ro, Seocho-gu
SEOUL
137-724
Republic Korea

12/11/2013

Truthful and Accurate Statement

[As required by 21 CFR 807.87(k)]

I certify that, in my capacity as Vice President of LG Electronics, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

(b) (6) [redacted]

Signature

(b) (6) [redacted]

Typed Name

12/11/2013

Date

*(Premarket Notification [510(k)] Number)

*For a new submission, leave the 510(k) number blank

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 62304:2006 Medical Device Software - Software Life Cycle

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#13-8	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: Guidance for the content of Premarket Submissions for Software Contained in Medical Devices

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
IEC 62304:2006 Medical Device Software - Software Life Cycle

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
ALL	ALL	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

❖ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

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Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

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 control number.

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 14971:2007 Medical devices - Application of risk management to medical devices

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#5-40	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

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SUMMARY REPORT TABLE

STANDARD TITLE
ISO 14971:2007 Medical devices - Application of risk management to medical devices

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
ALL	ALL	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

❖ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

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K103276

FEB - 8 2011

510(k) Summary
As required by 21 CFR §807.92(c)

Submitter

510(k) Owner:	Intel Corporation
Address:	1900 Prairie City Road, FM7-197, Folsom, CA 95630
Telephone:	916 847-7794
Contact Person:	Maureen Glynn
Date Prepared:	01/06/2011

Device Information

Trade Name:	Intel® Health Guide Express
Common Name:	Remote Patient Monitoring System
Classification Name:	Transmitters and Receivers, Physiological Signal, Radiofrequency (21 CFR 870.2910, Product Code DRG)

Substantial Equivalence is claimed to the following device:
1. Intel's Intel® Health Guide PHS6000 **(K080798, K083115 and K101178)**

Device Description

The Intel® Health Guide Express is a communication tool that allows caregivers to remotely access vital sign measurements of patients at home. The Intel® Health Guide Express is a software application running on a Commercial Off The Shelf (COTS) Personal Computer (PC). It collects measurements captured on commercially available wireless or tethered medical devices which are designed for home use and connection to a COTS PC. It displays the collected measurement on the PC, and securely stores the collected information locally on a memory device installed in the PC. The Intel® Health Guide Express also stores the information remotely on a host server, where the caregiver can view the measurement via the host server once synchronization between the host server and Intel® Health Guide Express has been completed. The Intel® Health Guide Express can be used to display educational and motivational content from the caregiver and can facilitate communication between the caregiver and patient via health wellness surveys and optional video conferencing.

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. It 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 Intel® Health Guide PHS Express system consists of the:

(1) Intel® Health Guide Express software application:

The software application captures, stores, displays and transmits information to a secure database on a host server running the Intel® Health Care Management Suite software via a standard telephone line or internet connection. The Intel® Health Guide Express software runs on a Commercial Off The Shelf (COTS) Personal Computer (PC).

(2) Intel® Health Care Management Suite software application:

The software application runs on a host server and allows caregivers to review patient vital signs on the secure website. The Intel® Health Care Management Suite allows for predefining upper and lower limits and, when either limit is exceeded, the system emails and/or pages the caregiver.

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.

Technological Characteristics

The Intel® Health Guide Express is substantially equivalent to the predicate device Intel® Health Guide PHS 6000 **(K080798, K083115 and K101178)** in terms of data collection software functionality, operating system for the patient device, 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, communication protocol, power source, and display method.

Table 1: Peripherals Comparison between the predicate device and the **Intel® Health Guide Express**

Physiological Parameter	Intel® Health Guide PHS6000 (K080798, K083115 and K101178)	Intel® Health Guide Express
Blood Pressure	A&D UA-767PC (K982481)	
Weight	A&D UC-321PBT (exempt)	
	A&D UC-321PL (exempt)	
Blood Glucose Level	Bayer Diagnostics Ascensia Breeze2 (K062347)	
	Bayer Diagnostics Ascensia Contour Blood Glucose Monitoring System (K062058)	
	LifeScan OneTouch Ultra Family of Blood Glucose Monitoring Systems (K043197)	
	LifeScan OneTouch Ultra 2 of Blood Glucose Monitoring Systems (K053529)	
Oxygen Saturation	Nonin 4100 Pulse Oximeter (K043359)	
	N/A	Onyx® II 9560 (K081285)
FEV/PEF	Microlife PF100 (K031024)	

Table 2: Hardware Comparison between the COTS PC meeting minimum specifications and the predicate device[1]

Hardware Parameter	Intel® Health Guide PHS6000 (K080798, K083115 and K101178)	COTS PC
Operating System	Microsoft Windows XP embedded	Microsoft Windows 7 (32-bit versions)
CPU Core Frequency	1.5 GHz	Minimum: 1.6 GHz (Single Core)
System Memory Size	512MB	Minimum: 1 Gbyte
Pointing Device	HID compliant pointing device	HID compliant pointing device
Available Storage Capacity	40GB	Minimum: 10 Gbytes
LAN Connection	Externally accessible RJ45 jack for 802.3 10/100 LAN interface.	Externally accessible RJ45 jack for 802.3 10/100 LAN interface.
Ports	4 USB Ports	Minimum: 2 USB Ports
SD Card Slot	N/A	Minimum: 1 memory card SDHC compliant with the SD Card Association 2.00 card specification, Class 4 or faster.
Wireless Peripheral Connection	Bluetooth 2.0 Interface	Bluetooth 2.0 Interface
Display	600 x 800 18 bit color	Minimum: 1024 x 600 24 bit color
Speakers	1 Mono	Minimum: 1 (mono)
Microphone	1 Mono	Minimum: 1 (mono)

[1]Differences are to accommodate the Microsoft Windows 7 operating system

K103276

Table 3: Main difference between the COTS PC meeting minimum specifications and the predicate device

Parameter	Intel® Health Guide PHS6000 (K080798, K083115 and K101178)	COTS PC
Safety Standard	ES60601-1:2005 Medical electrical equipment – Part 1: General requirements for basic and essential performance	UL 60950-1:2007 Information Technology Equipment – Safety – Part 1: General Requirements
Patient Leakage Current – From Patient connection to earth[1]	100µA	3.5mA

[1]This is not meant to be an exhaustive list of differences between ES60601-1 and UL 60950-1 but highlights the differences covered in the risk analysis for a COTS PC used with the Intel® Health Guide Express.

Safety and Efficacy

The Intel® Health Guide Express does not rely on an assessment of clinical performance data. The device will conform to FDA's recognized consensus standards and relies on its conformity to demonstrate the safety and efficacy. The device introduces no new questions concerning the safety or efficacy and is, therefore, substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Intel Corporation
c/o Ms. Maureen Glynn
1900 Prairie City Rd.
MS FM7-197
Folsom, CA 95630

FEB - 8 2011

Re: K103276
Trade Name: Intel Health Guide Express
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter and Receiver
Regulatory Class: Class II (two)
Product Code: DRG
Dated: January 10, 2011
Received: January 11, 2011

Dear Ms. Glynn:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K103276

510(k) Notification Submission – Abbreviated
Intel Corporation, Inc.
Intel® Health Guide Express

Indications for Use:

510(k) Number: _____

Device Name: Intel® Health Guide Express

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.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K103276

LG Electronics

UHCTX-MNL-01 v1.0

User Manual

UHCTX

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SW Requirements Specifications

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SW Architecture Design

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High Level Design

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LG Electronics

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LG Electronics

Verification Test Plan

LG SmartHealth Development

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Verification Test Report(15th)

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LG SmartHealth Usability Testing Report

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12/11/2013

Software Certificate

I, (b) (6) [redacted] certify that the information contained in this 510(k) application about the LG SmartHealth software is correct, and that the procedures described in Section 16 of this application will be used to re-test and re-validate this software when it is revised.

(b) (6)

[redacted]

Signature

(b) (6)

[redacted]

Typed Name

12/11/2013

Date

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance

Under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

(b) (4)

[redacted]

(b) (4)

[redacted]

EMERGO GROUP

K133997/S001

January 9, 2014

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Cardiac Diagnostics Devices Branch,
Division of Cardiovascular Devices
10903 New Hampshire Avenue
W066-1244
Silver Spring, Maryland 20993-0002

FDA CDRH DMC
JAN 10 2014
Received

Dear Oscar;

(b) (4)

[redacted]

Sincerely,

Diane Sudduth

Diane Sudduth
Senior Consultant, RA/QA

EMERGO GROUP

January 9, 2014

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Cardiac Diagnostics Devices Branch,
Division of Cardiovascular Devices
10903 New Hampshire Avenue
W066-1244
Silver Spring, Maryland 20993-0002

Dear Oscar;

(b) (4)

[redacted]

Sincerely,

Diane Sudduth

Diane Sudduth
Senior Consultant, RA/QA

5006-0710

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)*

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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Food and Drug Administration
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K133997/S002

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FDA CDRH DMC
APR 30 2014
Received

April 29, 2014

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Cardiac Electrophysiology and Monitoring Branch,
Division of Cardiovascular Devices
10903 New Hampshire Avenue
W066-1244
Silver Spring, Maryland 20993-0002

RE: **K133997 LG SmartHealth Application**

Dear Oscar;

(b) (4)

[redacted]

Sincerely,

Diane Sudduth

Diane Sudduth
Senior Consultant, RA/QA

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5006-0710

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EMERGO GROUP

April 29, 2014

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Cardiac Electrophysiology and Monitoring Branch,
Division of Cardiovascular Devices
10903 New Hampshire Avenue
W066-1244
Silver Spring, Maryland 20993-0002

RE: **K133997 LG SmartHealth Application**

Dear Oscar;

(b) (4)

[redacted]

Sincerely,

Diane Sudduth

Diane Sudduth
Senior Consultant, RA/QA

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510(k) Summary

for

LG SmartHealth

1. Submission Sponsor

LG Electronics
38 Baumoe-ro, Seocho-gu
Seoul, 137-724
Korea
Phone: +82-2-526-4527
Fax: +82-2-526-4370
Contact: Chang Hee Lee, Chief Research Engineer

2. Submission Correspondent

Emergo Group
816 Congress Avenue, Suite 1400
Austin, TX 78701
Cell Phone: (561) 305-5075
Office Phone: (512) 327.9997
Fax: (512) 327.9998
Contact: Dr. Diane Sudduth, Senior Consultant, QA
Email: project.management@emergogroup.com

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.

Section 11 – Device Description

Device Name: LG SmartHealth

Description of the Device:
"LG SmartHealth" is an application software ("application" or "app") intended to operate on the Android operating system ("OS") that can be loaded on commercially available tablet or smartphone. The scalability and differences between many tablets and smartphones today are not too great to allow this flexibility and option.

LG SmartHealth, an application for use by patients, supports the features of Measurement Management, Medication Management, Telemedicine, and Common Management, in interface with external 3rd party wireless medical devices and healthcare professional server solution.

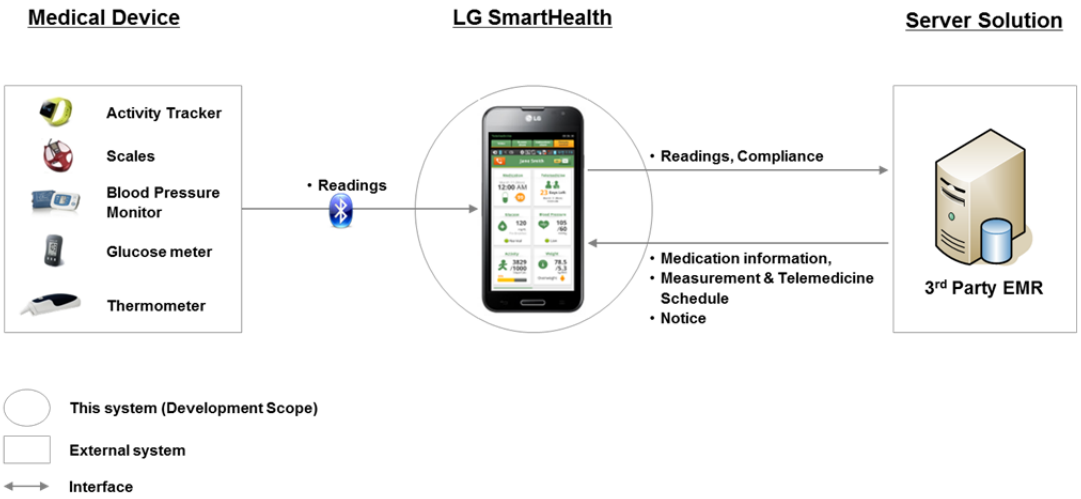

Figure 1 LG SmartHealth Operation Structure

LG SmartHealth 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 SmarthHealth loaded on the smartphone 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. LG SmartHealth plans to support the following sensor available medical devices, some initially, and then others as the technology become available:

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

Pressing the measurement guide button in LG SmartHealth provides step-by-step interactive help guide to the user.

The medical device takes a reading depending on the frequency previously established and LG SmartHealth fetches the information for the reading automatically. LG SmartHealth stores and displays the information on the tablet or smartphone and transmits the information to the 3rd party server and receive the information from the server via external interface.
LG SmartHealth encrypts the password using SHA256 algorithm b(4)Trade Secret Process-Product Specs [redacted], complying with HIPAA requirements.

These medical devices that are sensor, monitoring and recording devices will all be FDA cleared or FDA Class I, 510(k) Exempt products that are recommended by LG SmartHealth. A list of the acceptable medical devices that can be used with LG SmartHealth will be provided in the User's Manual.

Device Type	Vendor	Model	Connection	K Number
Blood Pressure Monitor	A&D Medical	UA-767PBT	Bluetooth wireless device	K043217
	FORA	P 20 Blood Pressure Monitor lU-RIGHT TD-3 132 Blood Pressure Monitor	Bluetooth wireless device	K092106
	FORA	D30F: Fora Comfort 2 in 1 blood glucose plus blood pressure monitoring system	Bluetooth wireless device	K080014
Glucose Monitor	Bayer HealthCare	Contour	Wired device	K121190
	LifeScan, a Johnson & Johnson company	OneTouch Ultra Mini	USB wired device	K061118
	CareSens	CareSens **N** LINK Blood Glucose Monitoring System	Bluetooth wireless device	K130696
Weight Scale	Biospace	H20	Bluetooth wireless device	K123228
	TANIA	BC590 BT	Bluetooth wireless device	K014009
Thermometer	Fora	IR20b Type I /II	Bluetooth wireless device	K090395
Activity Monitors	LG Electronics	LifeGram	Bluetooth wireless device	Exempt

Naming Convention:
Please note that LG SmartHealth may also be referred to as "SmartHealth", "SmartHealth app", or "LG SmartHealth" in many of the attached documents.

Indications 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).

Interface with the 3rd party server solution is required in order to provide the content and video conference.

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.

Mode of Operation and Mechanism of Action:

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Section 16 – Software Description

Device Name: LG SmartHealth

Device Description:

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

LG SmartHealth, an application for use by patients, supports the features of Measurement Management, Medication Management, Telemedicine, and Common Management, in interface with external 3rd party wireless medical devices and healthcare professional server solution.

LG SmartHealth 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 SmarthHealth loaded on the smartphone 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. LG SmartHealth plans to support the following sensor available medical devices, some initially, and then others as the technology become available:

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

Pressing the measurement guide button in LG SmartHealth provides step-by-step interactive help guide to the user.

The medical device takes a reading depending on the frequency previously established and LG SmartHealth fetches the information for the reading automatically. LG SmartHealth stores and displays the information on the tablet or smartphone and transmits the information to the 3rd party server and receive the information from the server via external interface.
LG SmartHealth encrypts the password using SHA256 algorithm (b) (4) [redacted], complying with HIPAA requirements.

These medical devices that are sensor, monitoring and recording devices will all be FDA cleared or FDA Class I, 510(k) Exempt products that are recommended by LG SmartHealth. A list of the acceptable medical devices that can be used with LG SmartHealth will be provided in the User's Manual.

16.1 Level of Concern:

Based on the Risk Management File (Exhibit 16-E) and the FDA Guidance document, *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*, issued on May 11, 2005, on levels of concern LG has determined that the software level of concern for the LG SmartHealth device is **Moderate**. The rationale for the decision on the software level of concern is shown below in the tables extracted from the Food and Drug Administration guidance document.

Table 16-A – Major Level of Concern Rationale

If the answer to any one question below is Yes, the Level of Concern for the Software Device is likely to be Major.		
Question	**Answer**	**Rationale**
1. Does the Software Device qualify as Blood Establishment Computer Software?	NO	The device is not a Blood Establishment Computer Software.
2. Is the Software Device intended to be used in combination with a drug or biologic?	NO	The device is not intended to be used in conjunction with a drug or biologic.
3. Is the Software Device an accessory to a medical device that has a Major Level of Concern?	NO	The device is not an accessory to a medical device that has a major level of concern.
4. Prior to mitigation of hazards, could a failure of the Software Device result in death or serious injury, either to a patient or to a user of the device? Examples of this include the following:		
a. Does the Software Device control a life supporting or life sustaining function?	NO	The device does not control a life sustaining or life supporting function.
b. Does the Software Device control the delivery of potentially harmful energy that could result in death or serious injury, such as radiation treatment systems, defibrillators, and ablation generators?	NO	The software does not control the delivery of potentially harmful energy that could result in a death or serious injury.
c. Does the Software Device control the delivery of treatment or therapy such that an error or malfunction could result in death or serious injury?	NO	The device does not control the delivery of treatment or therapy such that an error or malfunction could result in death or serious injury.
d. Does the Software Device provide diagnostic information that directly drives a decision regarding treatment or therapy, such that if misapplied it could result in serious injury or death?	NO	The software device processes (displays) digital information for the assessment of treatment only. This information does not directly mandate or control a decision regarding treatment or therapy as all digital information must be interpreted by a competent medical person together with any additional clinical information required for treatment.
e. Does the Software Device provide vital signs monitoring and alarms for potentially life threatening situations in which medical intervention is necessary?	NO	The device does not provide any vital signs monitoring and/or alarms.

Table 16-B – Moderate Level of Concern Rationale

If the answer to any one question below is Yes, the Level of Concern for the Software Device is likely to be Moderate.

Question	Answer	Rationale
1. Is the Software Device an accessory to a medical device that has a Moderate Level of Concern?	YES	The device is not an accessory to a medical device that has a major level of concern.
2. Prior to mitigation of hazards, could a failure of the Software Device result in Minor Injury, either to a patient or to a user of the device?	NO	A failure of the software device would not result in Minor Injury, either to a patient or to a user of the device if mitigation of hazards were not implemented.
3. Could a malfunction of, or a latent design flaw in, the Software Device lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury?	YES	A malfunction or a latent design flaw in the software device could lead to an erroneous diagnosis that would lead to a minor injury.

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LG Electronics

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Project Management Plan

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LG Electronics

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Configuration Management Plan

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b(4)Trade Secret Process-Product Specs

[redacted]

EMERGO

Emergo Group, Inc.
816 Congress Avenue, Suite 1400
Austin, Texas 78701
UNITED STATES
Telephone: +1 512 327 9997

K133997/S3

FDA CDRH DMC
NOV 20 2014
Received

November 19, 2014

U.S. Food and Drug Administration
Center for Devices and Radiological Health
U.S. Food and Drug Administration
Building WO66, Room 2558
10903 New Hampshire Avenue
Silver Spring, MD 20993
Attention: Ms. Linda Ricci

RE: K133997 LG SmartHealth – Supplement S2

Dear Ms Ricci:

(b) (4)

[redacted]

1-CD
50

EMERGO

Emergo Group, Inc.
816 Congress Avenue, Suite 1400
Austin, Texas 78701
UNITED STATES
Telephone: +1 512 327 9997

(b) (4)

[redacted]

Sincerely,

Diane Sudduth

Diane Sudduth
Sr. Regulatory Consultant
Emergo

b(4)Trade Secret Process-Product Specs

[redacted]

Emergo Group, Inc.
816 Congress Avenue, Suite 1400
Austin, Texas 78701
UNITED STATES
Telephone: +1 512 327 9997

November 19, 2014

U.S. Food and Drug Administration
Center for Devices and Radiological Health
U.S. Food and Drug Administration
Building WO66, Room 2558
10903 New Hampshire Avenue
Silver Spring, MD 20993
Attention: Ms. Linda Ricci

RE: K133997 LG SmartHealth – Supplement S2

Dear Ms Ricci:

(b) (4)

[redacted]

Emergo Group, Inc.
816 Congress Avenue, Suite 1400
Austin, Texas 78701
UNITED STATES
Telephone: +1 512 327 9997

(b) (4)
[redacted]

Sincerely,

Diane Sudduth
Sr. Regulatory Consultant
Emergo

b(4)Trade Secret Process-Product Specs
[redacted]

(b) (4) [redacted]

From: Ricci, Linda J [Linda.Ricci@fda.hhs.gov]
Sent: Friday, August 08, 2014 12:53 PM
To: Diane Sudduth @ Emergo Group; Tovar-Calderon, Oscar
Cc: Luciana Dall Astra @ Emergo Group
Subject: RE: K133997 b(4)Trade Secret Process-Product Specs

Hello Diane,

(b) (4) [redacted]

Best regards,
--Linda

Linda Ricci
Cardiac Diagnostic Devices Branch Chief
Division of Cardiovascular Devices
FDA/CDRH/ODE
10903 New Hampshire Ave, Bldg 66 Rm 1314
Silver Spring, MD 20993-0002
301-796-6325
linda.ricci@fda.hhs.gov

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-----Original Message-----
From: Diane Sudduth @ Emergo Group [mailto:DSudduth@emergogroup.com]
Sent: Friday, August 01, 2014 12:03 AM
To: Ricci, Linda J; Tovar-Calderon, Oscar
Cc: Luciana Dall Astra @ Emergo Group
Subject: RE: K133997 b(4)Trade Secret Process-Product Specs

Dear Linda,

(b) (4) [redacted]

(b) (4) [redacted]

Kindest regards,

Dr. Diane Sudduth, MS, MPH
EMERGO GROUP | Senior Regulatory Consultant
Phone: 561.305.5075
Online: http://www.EmergoGroup.com

From: Diane Sudduth @ Emergo Group
Sent: Tuesday, July 22, 2014 11:41 AM
To: Ricci, Linda J; Tovar-Calderon, Oscar
Cc: Luciana Dall Astra @ Emergo Group
Subject: RE: K133997 (b) (4) [redacted]

Linda,

(b) (4) [redacted]

Dr. Diane Sudduth, MS, MPH
EMERGO GROUP | Senior Regulatory Consultant
Phone: 561.305.5075
Online: http://www.EmergoGroup.com

From: Ricci, Linda J [Linda.Ricci@fda.hhs.gov]
Sent: Tuesday, July 22, 2014 11:15 AM
To: Diane Sudduth @ Emergo Group; Tovar-Calderon, Oscar
Cc: Luciana Dall Astra @ Emergo Group
Subject: RE: K133997 (b) (4) [redacted]

Diane,

(b) (4) [redacted]

Linda Ricci
Cardiac Diagnostic Devices Branch Chief
Division of Cardiovascular Devices
FDA/CDRH/ODE
10903 New Hampshire Ave, Bldg 66 Rm 1314
Silver Spring, MD 20993-0002
301-796-6325
linda.ricci@fda.hhs.gov

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-----Original Message-----
From: Diane Sudduth @ Emergo Group [mailto:DSudduth@emergogroup.com]
Sent: Tuesday, July 22, 2014 11:11 AM
To: Ricci, Linda J; Tovar-Calderon, Oscar
Cc: Luciana Dall Astra @ Emergo Group

Subject: RE: K133997 (b) (4) [redacted]

Linda,

(b) (4) [redacted]

Regards,

Dr. Diane Sudduth, MS, MPH
EMERGO GROUP | Senior Regulatory Consultant
Phone: 561.305.5075
Online: http://www.EmergoGroup.com

From: Ricci, Linda J [Linda.Ricci@fda.hhs.gov]
Sent: Tuesday, July 22, 2014 10:15 AM
To: Diane Sudduth @ Emergo Group; Tovar-Calderon, Oscar
Cc: Luciana Dall Astra @ Emergo Group
Subject: RE: K133997 (b) (4) [redacted]

Good morning Diane,

(b) (4) [redacted]

Linda Ricci
Cardiac Diagnostic Devices Branch Chief
Division of Cardiovascular Devices
FDA/CDRH/ODE
10903 New Hampshire Ave, Bldg 66 Rm 1314
Silver Spring, MD 20993-0002
301-796-6325
linda.ricci@fda.hhs.gov

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-----Original Message-----
From: Diane Sudduth @ Emergo Group [mailto:DSudduth@emergogroup.com]
Sent: Tuesday, July 22, 2014 8:56 AM
To: Ricci, Linda J; Tovar-Calderon, Oscar
Cc: Luciana Dall Astra @ Emergo Group
Subject: RE: K133997 (b) (4) [redacted]

Linda,

(b) (4) [redacted]

Kindest regards,

Dr. Diane Sudduth, MS, MPH
EMERGO GROUP | Senior Regulatory Consultant
Phone: 561.305.5075
Online: http://www.EmergoGroup.com

From: Diane Sudduth @ Emergo Group
Sent: Wednesday, June 25, 2014 3:26 PM
To: Ricci, Linda J; Tovar-Calderon, Oscar
Cc: Luciana Dall Astra @ Emergo Group
Subject: RE: K133997 (b) (4) [redacted]

Linda,

b(4)Trade Secret Process-Product Specs

Regards,

Dr. Diane Sudduth, MS, MPH
EMERGO GROUP | Senior Regulatory Consultant
Phone: 561.305.5075
Online: http://www.EmergoGroup.com

From: Ricci, Linda J [Linda.Ricci@fda.hhs.gov]
Sent: Wednesday, June 25, 2014 2:46 PM
To: Diane Sudduth @ Emergo Group; Tovar-Calderon, Oscar
Cc: Luciana Dall Astra @ Emergo Group
Subject: RE: K133997b(4)Trade Secret Process-Product Specs

HI Diane,

b(4)Trade Secret Process-Product Specs

Best Regards,

--Linda

Linda Ricci
Cardiac Diagnostic Devices Branch Chief
Division of Cardiovascular Devices
FDA/CDRH/ODE
10903 New Hampshire Ave, Bldg 66 Rm 1314
Silver Spring, MD 20993-0002
301-796-6325
linda.ricci@fda.hhs.gov

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-----Original Message-----
From: Diane Sudduth @ Emergo Group [mailto:DSudduth@emergogroup.com]
Sent: Wednesday, June 25, 2014 9:57 AM
To: Ricci, Linda J; Tovar-Calderon, Oscar
Cc: Luciana Dall Astra @ Emergo Group
Subject: RE: K133997 b(4)Trade Secret Process-Product Specs

Dear Linda,

b(4)Trade Secret Process-Product Specs

Kindest regards,

Dr. Diane Sudduth, MS, MPH
EMERGO GROUP | Senior Regulatory Consultant
Phone: 561.305.5075
Online: http://www.EmergoGroup.com

From: Ricci, Linda J [Linda.Ricci@fda.hhs.gov]
Sent: Wednesday, June 25, 2014 9:22 AM
To: Diane Sudduth @ Emergo Group; Luciana Dall Astra @ Emergo Group; Tovar-Calderon, Oscar
Subject: RE: K133997 b(4)Trade Secret Process-Product Specs

b(4)Trade

Linda Ricci
Cardiac Diagnostic Devices Branch Chief
Division of Cardiovascular Devices

FDA/CDRH/ODE
10903 New Hampshire Ave, Bldg 66 Rm 1314
Silver Spring, MD 20993-0002
301-796-6325
linda.ricci@fda.hhs.gov

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-----Original Message-----
From: Diane Sudduth @ Emergo Group [mailto:DSudduth@emergogroup.com]
Sent: Monday, June 23, 2014 6:00 PM
To: Ricci, Linda J; Luciana Dall Astra @ Emergo Group; Tovar-Calderon, Oscar
Subject: RE: K133997 (b) (4) [redacted]
Importance: High

Dear Linda,

(b) (4) [redacted]

Kindest regards,

Dr. Diane Sudduth, MS, MPH
EMERGO GROUP | Senior Regulatory Consultant
Phone: 561.305.5075
Online: http://www.EmergoGroup.com

From: Ricci, Linda J [Linda.Ricci@fda.hhs.gov]
Sent: Wednesday, June 18, 2014 4:52 PM
To: Luciana Dall Astra @ Emergo Group; Diane Sudduth @ Emergo Group; Tovar-Calderon, Oscar
Subject: Re: K133997 (b) (4) [redacted]

That will be great.

Thanks!

----- Original Message -----
From: Luciana Dall Astra @ Emergo Group [mailto:ldallastra@emergogroup.com]
Sent: Wednesday, June 18, 2014 04:14 PM
To: Ricci, Linda J; Diane Sudduth @ Emergo Group <DSudduth@emergogroup.com>; Tovar-Calderon, Oscar
Subject: RE: K133997 (b) (4) [redacted]

Good afternoon Linda,

(b) (4) [redacted]

Thanks!

Best regards,

Luciana Dall'Astra, PMP
EMERGO GROUP | International Project Manager
US Office: +1.512.600.7617

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-----Original Message-----
From: Ricci, Linda J [mailto:Linda.Ricci@fda.hhs.gov]
Sent: Wednesday, June 18, 2014 11:52 AM
To: Diane Sudduth @ Emergo Group; Tovar-Calderon, Oscar
Cc: Luciana Dall Astra @ Emergo Group
Subject: RE: K133997 (b) (4) [redacted]

Dear Diane,

(b) (4) [redacted]

Regards,
--Linda

Linda Ricci
Cardiac Diagnostic Devices Branch Chief
Division of Cardiovascular Devices
FDA/CDRH/ODE
10903 New Hampshire Ave, Bldg 66 Rm 1314 Silver Spring, MD 20993-0002
301-796-6325
linda.ricci@fda.hhs.gov

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-----Original Message-----
From: Diane Sudduth @ Emergo Group [mailto:DSudduth@emergogroup.com]
Sent: Wednesday, June 18, 2014 12:40 PM
To: Tovar-Calderon, Oscar; Ricci, Linda J
Cc: Luciana Dall Astra @ Emergo Group
Subject: RE: K133997(b) (4) [redacted]

Dear Linda,

(b) (4) [redacted]

Kindest regards,

Dr. Diane Sudduth, MS, MPH
EMERGO GROUP | Senior Regulatory Consultant
Phone: 561.305.5075
Online: http://www.EmergoGroup.com

From: Diane Sudduth @ Emergo Group
Sent: Tuesday, June 17, 2014 9:13 AM
To: Tovar-Calderon, Oscar
Cc: Luciana Dall Astra @ Emergo Group
Subject: RE: K133997 (b) (4) [redacted]

Dear Oscar,

(b) (4) [redacted]

Regards,

Dr. Diane Sudduth, MS, MPH
EMERGO GROUP | Senior Regulatory Consultant
Phone: 561.305.5075
Online: http://www.EmergoGroup.com

510(k) Summary

for

LG SmartHealth

1. Submission Sponsor

LG Electronics
38 Baumoe-ro, Seocho-gu
Seoul, 137-724
Korea
Phone: +82-2-526-4527
Fax: +82-2-526-4370
Contact: Chang Hee Lee, Chief Research Engineer

2. Submission Correspondent

Emergo Group
816 Congress Avenue, Suite 1400
Austin, TX 78701
Cell Phone: (561) 305-5075
Office Phone: (512) 327.9997
Fax: (512) 327.9998
Contact: Dr. Diane Sudduth, Senior Consultant, QA
Email: project.management@emergogroup.com

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.

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)*

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)*

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PRAStaff@fda.hhs.gov

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