DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

June 3, 2016

Honeywell Hommed, LLC
% John Ziobro
Spectramedex, LLC
3215 Gold Road
Delafield, Wisconsin 53018

Re: K153719
Trade/Device Name: LifeStream™ 5
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter and Receiver
Regulatory Class: Class II
Product Code: DRG
Dated: April 28, 2016
Received: May 2, 2016

Dear John Ziobro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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

Sincerely yours,

Shawn W. Forrest -S
2016.06.03 10:52:43 -04'00'

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153719

Device Name
LifeStream™ 5

Indications for Use *(Describe)*
LifeStream 5 is a stand alone, prescription-based software program designed to operate in a clinical setting by healthcare professionals. It consists of a hosted web server, a hosted database server and two types of client interfaces - one that is provided by Windows client and one that is provided by a web client interface.

LifeStream software's intended use is to retrospectively receive, display and store monitored vital signs parameters and related data. Such data includes patient blood pressure (NIBP), oxygen saturation (SpO2), weight, blood glucose, temperature, dispensed medicine, ECG, peak flow, prothrombin time and retrospective PERS messages.

LifeStream retrospectively displays the data, user-defined data alerts and system alerts for review and interpretation by a healthcare professional. LifeStream is not intended for emergency use or real-time monitoring.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Honeywell
Life Care Solutions
Honeywell HomMed, LLC

Honeywell HomMed LifeStream™ 5 510(k) Summary Statement

Summary Date: 12/17/2015

Applicant Name: Honeywell HomMed, LLC
and Address: 3400 Intertech Drive, Suite 200
Brookfield, Wisconsin 53045
Ph: (262) 252-783-5440
Establishment Registration #3004183721

Manufacturing Site: Honeywell HomMed, LLC
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Establishment Registration #3004183721

Corporate Contact: Greg Lillegard, Operations, Vice President
Honeywell HomMed, LLC
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Contact Person: John Ziobro
Principal Consultant
SpectraMedEx, LLC
3215 Golf Road, #149
Delafield, WI 53018
Ph: (262) 719-89228
Fax: (262) 968-2915

Model Number LifeStream™ 5

Common Name: Patient Vital Signs Monitor Viewing Station

Brand/Trade Names: LifeStream™ 5

Reason for Traditional 510(k) : New Submission

Indications For Use:

LifeStream 5 is a stand alone, prescription-based software program designed to operate in a clinical setting by healthcare professionals. It consists of a hosted web server, a hosted database server and two types of client interfaces - one that is provided by Windows client and one that is provided by a web client interface.

LifeStream software's intended use is to retrospectively receive, display and store monitored vital signs parameters and related data. Such data includes patient blood pressure (NIBP), oxygen saturation (SpO_2), weight, blood glucose, temperature, dispensed medicine, ECG, peak flow, prothrombin time and retrospective PERS messages.

LifeStream retrospectively displays the data, user-defined data alerts and system alerts for review and interpretation by a healthcare professional. LifeStream is not intended for emergency use or real-time monitoring.

Classification Information:

Regulation Number	Review Panel	Product Code	Classification Name	Device Class
870.2910	Cardiovascular	DRG	Radiofrequency physiological signal transmitter and receiver	II
Subsequent product codes also supported by LifeStream by means of separate medical devices				
870.1130	Cardiovascular	DXN	Noninvasive blood pressure measurement system	II
880.2700	General Hospital	FRI	Patient Weight Scale	I
870.2700	Anesthesiology	DQA	Oximeter	II
862.1345	Clinical Chemistry	NBW	Glucose Test System	II
868.1860	Anesthesiology	BZH	Meter, Peak Flow, Spirometry	II
864.7750	Hematology	GJS	Test, Time, Prothrombin	II
890.5050	Physical Medicine	NXB	Dispenser, solid medication	I
880.6310	General Hospital	OUG	Medical Device Data System	I
880.2910	General Hospital	FLL	Clinical Electronic Thermometer	II
870.2340	Cardiovascular	DPS	Electrocardiograph	II

Predicate Device(s): Central Station, Version 4.0, K072272, branded as the LifeStream™ 4.0.

Predicate Classification Information:

Regulation Number	Review Panel	Product Code	Classification Name	Device Class
870.1130	Cardiovascular	DXN	Noninvasive blood pressure measurement system	II

Device Description:
LifeStream 5 is a stand alone, prescription-based software program designed to operate in a clinical setting by healthcare professionals. It consists of a hosted web server, a hosted database server and two types of client interfaces, one that is provided by Windows client and one that is provided by a web client interface. LifeStream 5, like the predicate LifeStream 4.0, is configured to accept patient data that is acquired periodically and displayed retrospectively from Honeywell HomMed Patient Monitors (e.g. Genesis DM, Genesis Touch). LifeStream 5 can also interface with 3rd party compatible medical device data systems (e.g. Govsphere Tablet, Govsphere TV). LifeStream 5 has the same intended use as the predicate, LifeStream 4.0. LifeStream 5, like LifeStream 4.0 is not intended for emergency use or real-time monitoring. Both are designed to retrospectively receive, display and store scheduled vital sign parameters and related data. Such data includes patient blood pressure (NIBP), oxygen saturation (SpO_2), weight, blood glucose, temperature, dispensed medicine, ECG, peak flow, prothrombin time and retrospective PERS messages.

Technological Characteristics
Both the subject device and predicate device are software programs" with substantially equivalent intended uses, users, and use environments that were written in C# that operate on PCs powered by AC Mains / battery power.

Predicate Device Comparison:
As shown in the tables below, LifeStream 5 is substantially equivalent in operation and performance to predicate the LifeStream Central Station 4.0 cleared under K072272. See also the Substantial Equivalence (SE) table, attached.

LifeStream Manager 4.0 Predicate				
	Manufacturer, Model	**Description**	**510(k) Number**	**Communication Method**
Vital Signs Data Acquisition (communicates with Monitors)				
Blood Pressure Systolic mmHg, Diastolic mmHg	A&D Digital UA-767 Plus BT-Ci	noninvasive blood pressure monitor	K040371	Bluetooth
	A&D Digital UA-767BT	noninvasive blood pressure monitor	K040371	Bluetooth
Pulse Oximetry Pulse Rate and Oxygen Saturation	Contec CMS50EW	Fingertip pulse oximeter	K090671	Bluetooth
	Nonin Onyx II 9560	Fingertip pulse oximeter	K081285	Bluetooth
	ChoiceMed MD300C318	Fingertip pulse oximeter	K092620	Bluetooth
Weight Pounds, lbs or Kilograms, Kgs	Honeywell HomMed 5002100A1	Scale	exempt	Bluetooth
	A&D Medical UC-321PBT	Scale	exempt	Bluetooth
	NCI Technology Inc. Accuro HRS305	Hand rail scale	exempt	Bluetooth
Blood Sugar mg/dL	Entra Health Systems MyGlucoHealth (US) MGH-BT1	Glucometer	K081703	Bluetooth
ECG	No longer manufactured	Electrocardiograph	N/A	N/A
Vital Signs Monitors/Medicine Dispenser (Communicates with Honeywell Secure Servers				
Genesis DM	Honeywell HomMed	Single/Multi-patient Monitoring System	K101242	Web Services
Genesis Touch	Honeywell HomMed	Single-patient Monitoring System	K141792 K112858	Web Services
Medicine Dispenser	MedPartner	Daily Activity Assist Device	K053122	Web Services
Clinician Work Station				
Disease Management Protocol	Pre-defined by User	Users: Various	N/A	Honeywell Secure Servers (central servers)
Graphical user interface	Honeywell HomMed, LifeStream Management Suite 4.0 (central viewing station)	Windows-based Software Application used by Healthcare Provider to manage data received from Genesis Monitor s	K072272	Honeywell Secure Servers (central servers)

LifeStream Manager 5.0 Subject Device				
Vital Signs Data Acquisition				
	Manufacturer, Model	**Description**	**510(k) Number**	**Communication to Monitor**
Blood Pressure Systolic mmHg, Diastolic mmHg	A&D Digital UA-767 Plus BT-Ci	noninvasive blood pressure monitor	K040371	BlueTooth
	A&D Digital UA-767BT	noninvasive blood pressure monitor	K040371	BlueTooth
Pulse Oximetry Pulse Rate and Oxygen Saturation	Contec CMS50EW	Fingertip pulse oximeter	K090671	BlueTooth
	Nonin Onyx II 9560	Fingertip pulse oximeter	K081285	BlueTooth
	ChoiceMed MD300C318	Fingertip pulse oximeter	K092620	BlueTooth
Weight Pounds, lbs or Kilograms, Kgs	Honeywell HomMed 5002100A1	Scale	exempt	BlueTooth
	A&D Medical UC-321PBT	Scale	exempt	BlueTooth
	NCI Technology Inc. Accuro HRS305	Hand rail scale	exempt	Bluetooth
Blood Sugar mg/dL	Entra Health Systems MyGlucoHealth (US) MGH-BT1	Glucometer	K081703	BlueTooth
MDDS Communications Device	Govsphere VITAL Tablet; Govsphere VITAL TV	Medical device data system	exempt	BlueTooth
Temperature	Exergen Temporal Thermometer	Temporal scanner thermometer	K011291	Wire
ECG	et medical devices SpA ECG@home	Electrocardiograph	K091054	N/A
Vital Signs Monitors/Medicine Dispenser (Communicates with Honeywell Secure Servers				
Genesis DM	Honeywell HomMed	Single/Multi-patient Monitoring System	K101242	Web Services
Genesis Touch	Honeywell HomMed	Single-patient Monitoring System	K141792 K112858	Web Services
Medicine Dispenser	MedPartner	Daily Activity Assist Device	K053122	Web Services
Clinician Work Station				

Disease Management Protocol	Pre-defined by Honeywell HomMed or/and User	Users: Various Honeywell: COPD, Diabetes, CHF	N/A	
Graphical user interface	Honeywell HomMed, LifeStream Management Suite 5.0 (central viewing station)	Windows-based Software Application or Web-based used by Healthcare Provider to manage data received from Genesis Monitor s and compatible 3rd party monitors	Subject Device	Honeywell Secure Servers (central servers)

Substantial Equivalence (SE) table

Predicate Device(s)		**510(k) Application**
Feature/ Function	**Central Station v4.0 branded LifeStream Manager 4.0; K072272**	**LifeStream Manager 5.0 Subject Device**
GENERAL DESCRIPTIONS		
Intended Use / Indications for Use	Central Station's intended use is to retrospectively receive, display and store monitored vital signs parameters and related data. Central Station displays the data and system alerts for review and interpretation by a healthcare professional. Central Station is not intended for emergency use or real-time monitoring.	LifeStream 5 is a stand alone, prescription-based software program designed to operate in a clinical setting by healthcare professionals. It consists of a hosted web server, a hosted database server and two types of client interfaces - one that is provided by Windows client and one that is provided by a web client interface. LifeStream software's intended use is to retrospectively receive, display and store monitored vital signs parameters and related data. Such data includes patient blood pressure (NIBP), oxygen saturation (SpO_2), weight, blood glucose, temperature, dispensed medicine, ECG, peak flow, prothrombin time and retrospective PERS messages. LifeStream retrospectively displays the data, user-defined data alerts and system alerts for review and interpretation by a healthcare professional. LifeStream is not intended for emergency use or real-time monitoring.
User Population	Health care professionals	Health care professionals
Environment of Use	Intended to be used in a healthcare related environment by healthcare providers.	Intended to be used in a healthcare related environment by healthcare providers.
Content	For informational purposes only and does not provide professional medical advice, diagnosis, or treatment.	For informational purposes only and does not provide professional medical advice, diagnosis, or treatment.
Contraindications and Use Limitations	LifeStream Manager 4.0 is not intended for emergency use or real-time monitoring. LifeStream Manager 4.0 is not intended to be accessed or used directly by patients	LifeStream is NOT an emergency medical response system. LifeStream does NOT provide real-time, critical-care monitoring of patient vital signs. Reports generated by LifeStream are NOT intended to be used as a patient medical record or patient vital sign reporting documentation. LifeStream does not analyze or perform calculations on the data collected by the peripheral devices.
Regulation Number & Product Code	870.1130, DXN, Class II	870.2910, DRG, Class II Subsequent/additional regulation numbers & codes 870.1130 DXN 880.2700 FRI 870.2700 DQA 862.1345 NBW 868.1860 BZH 864.7750 GJS 890.5050 NXB 880.6310 OUG 880.2910 FLL 870.2340 DPS
Hardware-Related Technological Characteristics		
Hardware Platform	**Commercial PC** Computer/Processor: 1 GHz or faster x86- or x64-bit processor Memory: 1 gigabyte (GB) RAM (32-bit); 2 gigabytes (GB) RAM (64-bit) Hard Disk: 1 gigabyte (GB) of disk space available Display: 1024x768 or higher resolution monitor	**Commercial PC** Computer/Processor: 1 GHz or faster x86- or x64-bit processor Memory: 1 gigabyte (GB) RAM (32-bit); 2 gigabytes (GB) RAM (64-bit) or greater Hard Disk: 1 gigabyte (GB) of disk space available Display: 1024x768 or higher resolution monitor

Predicate Device(s)		510(k) Application
Feature/ Function	**Central Station v4.0 branded LifeStream Manager 4.0; K072272**	**LifeStream Manager 5.0 Subject Device**
Hardware Compliance/ Conformity Standards	The medical device is software installed or accessed using off-the-shelf PCs and not subject to EN60601-1-2.	The medical device is software accessed using off-the-shelf PCs and not subject to IEC 60601-1 & 60601-1-2.
Hardware Power Supply	AC Mains or battery	AC Mains or battery
Software-Related Operating Environment / Principles / Technological Characteristics		
Operating System	Operating System Windows XP with all available Microsoft service packs Windows Vista Windows 7 NET Framework version 2.0 Web browser: Internet Explorer 9	Operating System Windows Vista Windows 7 NET Framework version 2.0 Web browser: Internet Explorer 9 or higher
Peripherals	Internet connection; mouse or compatible pointing device	Internet connection; mouse or compatible pointing device
Programming Language	C#	C#
Communications into LifeStream Database Server from the Patient Monitoring System		
Transmission	POTS, Internet, SkyTel, PageNet	POTS, Internet
Output Devices	Fax, Printer, email	Fax, Printer, email
Communications out of LifeStream Database Server to the Patient Monitoring System		
Transmission	Web services (	Web services
Output Devices	Fax, Printer, email	Fax, Printer, email
User Interface	LifeStream Windows Client	LifeStream Windows Client and LifeStream Web Client
Database	Honeywell hosted Database service	Honeywell hosted Database service
FDA Software Level of Concern	Moderate	Moderate
Clinical Features of the Software		
Patient Task Screen	Alert Limits, Vitals Current Status, Demographics, Equipment & Question Setup/Configuration, Patient Information, Patient List, Vitals Tabular Trends, Patient Messages	Alert Limits, Vitals Current Status, Demographics, Equipment & Question Setup/Configuration, Patient Information, Patient List, Vitals Tabular Trends, Questions graph, Patient Messages
Organization Screen	Care Providers, Diagnoses, Equipment List, Insurers, Medications, Sites/Categories, System Configuration, Users	Care Providers, Diagnoses, Equipment List, Insurers, Medications, Sites/Categories, System Configuration, Users
Tools Screen	Change Password, System Log, User Settings	Change Password, System Log, User Settings
System Screen	Logoff, Exit	Logoff, Exit
Standard Patient Data Displayed	Weight, Systolic, Diastolic, SpO2, Heart rate, Temperature, Questions & Question responses	Weight, Systolic, Diastolic, SpO2, Heart rate, Temperature, Questions & Question responses, Pain Answers
Optional Patient Data Displayed	Blood glucose, Spirometry, PT/INR and ECG, ID Card Reader, MedPartner	Blood glucose, Spirometry, PT/INR and ECG, ID Card Reader

Predicate Device(s)		510(k) Application
Feature/ Function	**Central Station v4.0 branded LifeStream Manager 4.0; K072272**	**LifeStream Manager 5.0 Subject Device**
Data Alert Status	**Vital Signs:** Red - Limit violation Brown - LifeStream MobileHelp Mobile Personal Emergency Response System (PERS) notifications Blue - No limits set (monitor only) Orange - Transmit error, Null (empty) data packet Yellow - Missing data (one or more, but not all vitals are missing) Green - Data complete & Vital sign readings are within set limits Purple - Vital signs for this patient are on hold **MedPartner:** Red - Missed Blue - Unauthorized Orange - Null (empty) data packet or No Data Received (NDR) Yellow – Out of Sync (LifeStream/MedPartner synchronization error) Green - Conformance	**Vital Signs:** Dark Red (H) – Limit violation (highest level of user defined alert) Medium Red (M) – Medium Alert (medium level of user defined alert) Light Red (L) – Low Alert (lowest level of user defined alert) Brown - LifeStream MobileHelp Mobile Personal Emergency Response System (PERS) notifications Blue - No limits set (monitor only) Orange - Transmit error, Null (empty) data packet Yellow - Missing data (one or more, but not all vitals are missing) Green - Data complete & Vital sign readings are within set limits Purple - Vital signs for this patient are on hold
Window Layout (regardless if accessed via Windows or Web Server)	Title Bar - Application name, selected patient and window control buttons Menu Bar - Menu titles Tool bar – Navigation & toolbar buttons Sites/Categories Drop down box Trend Days Selector (optional) Minimize, Maximize & Close - Minimizes, maximizes and closes the application window Main Window - The overall display of data Status Bar - Displays the current quantity of each unacknowledged readings Navigation Pane - Provides the most common options available for each user's role and privileges.	Title Bar - Application name, selected patient and window control buttons Menu Bar - Menu titles Tool bar – Navigation & toolbar buttons Sites/Categories Drop down box Trend Days Selector (optional) Minimize, Maximize & Close - Minimizes, maximizes and closes the application window Main Window - The overall display of data Status Bar - Displays the current quantity of each unacknowledged readings Navigation Pane - Provides the most common options available for each user's role and privileges.
Check New Readings	Automatic or Manual	Automatic or Manual
Vital Signs Transmission Times	Scheduled – one to four per day Monitor configuration can be updated from monitor and/or LifeStream	Scheduled – one to four per day Monitor configuration can be updated from monitor and/or LifeStream
Alert Limits	Manual- User configured	Manual- User configured, with three levels: low, medium and high alerts. Two additional levels have been added to allow the healthcare provider to further divide the red alerts.
Vital Signs Status Triage	Listed in order of oldest and most critical (# of vitals outside set parameters)	Listed in order of oldest and most critical (# of vitals outside set parameters)
Vital Signs Reports (Read/write capability)	Patient Lists, patient information, tabular trends, multi-patient trends, patient compliance (vital signs), equipment history (all enabled equipment, single item history, patient's equipment history), alert limit history, graphical trends and notes	When accessed via the LifeStream Windows Client: Patient Lists, patient information, tabular trends, multi-patient trends, patient compliance (vital signs), equipment history (all enabled equipment, single item history, patient's equipment history), alert limit history, graphical trends and notes (read + write underlying data) When accessed via the LifeStream Web Client: Read underlying data only)
Equipment Tracking	If enabled, the system allows users to track monitors, ID cards, scales, pagers and MedPartner-K053122	If enabled, the system allows users to track monitors, ID cards, scales
Disease Management Protocols	End-User Configurable	End-User Configurable, Honeywell Pre-defined

Predicate Device(s)		510(k) Application
Feature/ Function	**Central Station v4.0 branded LifeStream Manager 4.0; K072272**	**LifeStream Manager 5.0 Subject Device**
Additional Software Features	• LifeStream Connect: Streamline workflows by integrating with EHR and POC applications through HL7 standard interfaces.	• LifeStream Analytics: Customizes and assesses telehealth program data to determine return on investment (ROI) and resource/care management. • LifeStream Connect: Streamline workflows by integrating with EHR and POC applications through HL7 standard interfaces. • LifeStream View: Browser-based interface allows care providers and family members to securely access patient data at any time. LifeStream MobileHelp MH3 Care Provider Portal: Access patient information for those using a Mobile Personal Emergency Response (mPERS) device.
Compatible Patient Monitoring Systems		
Compatibility	Sentry Monitors: K993938, K004044, K014025, K040651, K061088 Genesis Monitors: K040799, K061087, Genesis DM Monitors: K101242 Genesis Touch Monitors: K112858, K141792	Genesis DM Monitors: K101242 Genesis Touch Monitors: K112858, K141792 Govsphere VITAL Tablet: MDDS (exempt) Govsphere VITAL TV: MDDS (exempt)
Administration		
System Administration Reports	Audit logs - Monitors/ID cards Report, Site Report, Users Report and System Status Report (read underlying data)	When accessed via the LifeStream Windows Client: Audit logs - Monitors/ID cards Report, Site Report, Users Report and System Status Report (read underlying data) When accessed via the LifeStream Web Client: No access for these System Administration Reports.
System Log	Presents a list of database and communication server errors	Presents a list of database and communication server errors
System Configuration	Ability to enter configuration information related to Skytel, Data Export, Paging and Equipment tracking options; Enable/disable Outcomes Questionnaire functionality	Ability to enter configuration information related to Data Export and Equipment tracking options; Enable/disable Outcomes Questionnaire functionality
System Security		
System Security & Access Control	PIN & Username & password – Single Login for Dual role Administrator/Clinician Smart Passwords	PIN (with check digit functionality) & Username & password – Single Login for Dual role Administrator/Clinician Smart Passwords
Audit Logging	Date, Time, User I.D. • Medications • Diagnoses • Monitor/ID card assignments • All responses to vital signs • Configuration • MedPartner data	Date, Time, User I.D. • Medications • Diagnoses • Monitor/ID card assignments • All responses to vital signs Configuration
Privacy	Roles and Permissions Idle session limit	Roles and Permissions Idle session limit
Software Updates	Update software via update server	Update software via update server
Data Integrity & Protection	Encrypted in transit and storage. The encryption protocol is a function of the Patient Monitoring system. The data integrity is included as part of the encryption algorithm. Data hosting database is firewall and antivirus protected.	Encrypted in transit and storage. The encryption protocol is a function of the Patient Monitoring system. The data integrity is included as part of the encryption algorithm. Data hosting database is firewall and antivirus protected.
HIPAA Compliant	Yes	Yes

Performance / Bench Testing

Both the subject device and predicate device are software programs that were developed in the same facility, by the same software engineers, using same or equivalent testing protocols. The applicable test methods include the following:

- Functional testing of each functional requirement
- Validation testing of complete systems
- Automated regression testing
- Black box testing
- Localization testing
- Deployment testing
- External evaluation by Honeywell clinical team

Conclusions:

Honeywell HomMed, LLC, believes the proposed LifeStream 5 device under review and the predicate device (LifeStream 4) are substantially equivalent in their intended use, intended users, intended use environment and indications for use. Furthermore, both systems have the same/equivalent technological characteristics, physical characteristics, labeling and safety standards. The differences that exist between the devices, relating to the ability to access the software program via the web (rather than just via Windows, the addition of Honeywell defined disease management protocols and the ability to interface with 510(k) exempt third-party MDDS systems do not affect the relative safety and/or effectiveness