APR 1 4 2014

Entra Health Systems LLC
3111 Camino del Rio North
Suite 101
San Diego, CA 92108
Main 877 458 2646
Fax 619 584 4504

K132930

December 26, 2013

510(k) Summary
(in accordance with 21 CFR 807.92)

A. Submitter: Entra Health Systems

B. Address: 3111 Camino Del Rio North
Suite 101
San Diego CA 92108

C. Corporate Contact: Richard Strobridge, CEO
Entra Health Systems

D. Telephone: Ph: 877-458-2646
Fax: 619-584-4504

E. Submission Contact: Emily Davis, Project Manager
Entra Health Systems
3111 Camino Del Rio North
Suite 101
San Diego CA 92108
Ph: 877-458-2646
edavis@entrahealthsystems.com

F. Trade Name: MyHealthPoint TeleHealth Manager

G. Predicate Device(s):
- Vignet TeleHealth Manager, K113446
- Honeywell Genesis DM Monitor, K101242
- Verizon Wireless Converged Health Management Device, K122458

H. Common Name: Telemedicine System

I. Classification:

Regulation Number	Product Code	Classification Name	Device Class
870.2910	DRG	Radiofrequency Physiological Signal Transmitter and Receiver	II
Medical device product codes also supported by MyHealthPoint Telehealth Manager by means of separate medical devices			
862.2100	JQP	Calculator/Data Processing Module	I
870.1130	DXN	Noninvasive Blood Pressure Measurement	II
870.2700	DQA	Oximeter	II
880.2910	FLL	Thermometer, Electronic, Clinical	II
870.2340	DPS	Elecrocardiograph	II
870.2360	DRX	Electrocardiograph electrode	II
890.5060	NXB	Medication Reminder	I
880.2700	FRI	Patient Weight Scale	I
880.6310	OUG	Medical device data system	I

Entra Health Systems

Entra Health Systems LLC
3111 Camino del Rio North
Suite 101
San Diego, CA 92108
Main 877 458 2646
Fax 619 584 4504

J. Device Description

The MyHealthPoint Telehealth Manager is a software platform accessible via PC or mobile smart phone that collects member's biometric data such as activity, blood pressure, blood glucose, ECG, body temperature, body composition/weight and pulse oximetry, and has the ability to send medication reminders. The MyHealthPoint TeleHealth Manager can be used by patients during their daily lives to collect biometric readings from various personal health monitors from a variety of manufacturers to assist in maintaining wellness regimens and the clinical monitoring of patients with chronic disease. The system can be accessed by members, clinicians and caregivers for analysis and intervention using standard digital communication technologies and protocols. The MyHealthPoint Telehealth Manager is intended for use in remote monitoring of patient biometrics and supports messaging between member's, clinicians and caregivers. In addition to monitoring, MyHealthPoint TeleHealth Manager supports reminders, alerts, and online graphical reports to help patients and their healthcare professionals better understand and manage their conditions.

The supported cleared, home-monitoring devices currently marketed with the MyHealthPoint TeleHealth Manager for wireless collection of data and physiological information is in the table below and the systems Architecture is explained on page 3.

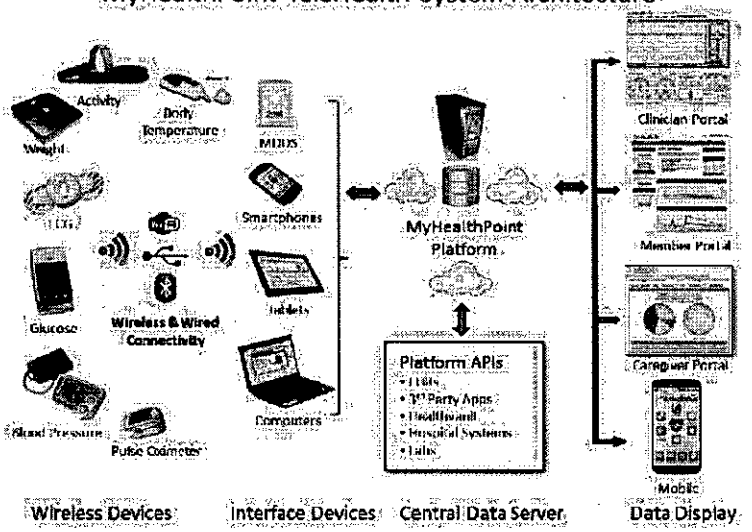
No.	Vital Signs/ Product Code	Measurement	Vital Signs Equipment Manufacturers/Models (510k)	Connection Type to MyHealthPoint
1	Glucose	Blood glucose (mg/dl or mmol/L)	Entra Health Systems, MGH-BT1, K081703	Bluetooth through Mobile App, USB or MDDS Device
2	Weight	Weight Scale ((lbs. or Kgs.)/Body Composition	AnD, UC-321PBT	Bluetooth through MDDS Device
			Omron, HBF-206IT	Bluetooth through MDDS Device
			Fora Weight Scale, W310b	Bluetooth through MDDS Device
			Withings Wi-Fi Scale, WS-50	Wifi through Home Router
3	Pulse Oximetry	Pulse Rate and Oxygen Saturation	Nonin, 9560BT (K09336)	Bluetooth through MDDS Device
4	Blood Pressure	Blood pressure (Systolic (mmHg), Diastolic (mmHg))	AnD,UA-767BTB (K043217)	Bluetooth through MDDS Device
			Omron BP Monitor, BP792IT (K131742)	Bluetooth through MDDS Device
			Fora BP Monitor, P20b (K092106)	Bluetooth through MDDS Device
5	Pedometer	Steps, Calories, Sleep	Fitbit, Flexx, Zip, One, Force	Bluetooth through MDDS Device and USB
			BodyMedia, Link, Core	Bluetooth through MDDS Device and USB
6	ECG	Heart Rate, Respiration	Zephyr , Bioharness 3.1 9607.0090 (K113045)	Bluetooth through MDDS Device
7	Thermometer	Body Temperature (Celsius or Fahrenheit)	For a, IR20b (K090395)	Bluetooth through MDDS Device

Entra Health Systems

Entra Health Systems LLC
3111 Camino del Rio North
Suite 101
San Diego, CA 92108
Main 877 458 2646
Fax 619 584 4504

8	Transfer of Data	Medical Device Data System	Qualcomm 2Net, 65-KA123	Receives Bluetooth and sends Cellular
9	Medication Reminder	Member has the optional ability to add medications or products they are using with a reminder sent by SMS or email.	Entra Health Systems	Software component only.

MyHealthPoint TeleHealth System Architecture



K. Intended Use

The MyHealthPoint Telehealth Manager is an accessory software that wirelessly, collects, records and transmits biometric data (including glucose, blood pressure, weight, body composition, activity, body temperature, ECG and pulse oximeter readings) from a variety of supported home-monitoring devices as well as supporting manual uploading of data. The MyHealthPoint application uses the same data repository platform that is already cleared, MyGlucoHealth Software System (K081703).

MyHealthPoint TeleHealth Manager is intended to be used by patients in non-clinical settings (e.g. home) to collect, record and transmit their biometric data to a remote secure server. Stored data is accessible by healthcare professionals and caregivers for analysis, messaging and intervention using standard digital communication technologies and protocols. Patients may also view the data to assist in self-management of their specific health condition. The MyHealthPoint Telehealth Manager is intended to be used in combination with a variety of external vital sign devices.

The MyHealthPoint Telehealth Manager is intended to be used by patients identified by their healthcare organization that would benefit from remote monitoring. It is not intended as a replacement of the oversight of healthcare professionals nor does it provide "real-time" or emergency monitoring. It does not measure, interpret or make any decisions on the data that it conveys.

L. Predicate Devices

The MyHealthPoint Management System is substantially equivalent to the following FDA cleared predicate devices:

Entra Health Systems LLC
3111 Camino del Rio North
Suite 101
San Diego, CA 92108
Main 877 458 2646
Fax 619 584 4504

Predicate #1

510(k) Number:	K113446
Trade Name:	Vignet TeleHealth Manager
Manufacturer:	Vignet Inc.
Classification Name:	Radiofrequency Physiological Signal Transmitter and Receiver
Common/Usual Name:	Telemedicine System
Regulation Number:	870.2910
Product Codes:	DRG
Subsequent Product Codes:	DXN, NBW, FRW
Classification:	Class II

Predicate #2

510(k) Number:	K101242
Trade Name:	Genesis DM Monitor
Manufacturer:	Honeywell HomMed, LLC
Classification Name:	Radiofrequency Physiological Signal Transmitter and Receiver
Common/Usual Name:	Patient Vital Signs Monitor
Regulation Number:	870.2910
Product Codes:	DRG
Subsequent Product Codes:	DXN, DQA, FRI, NBW, BZH, FLL, GJS, DPS, NXB
Classification:	Class II

Predicate #3

510(k) Number:	K122458
Trade Name:	Verizon Wireless Converged Health Management (CHM) Device
Manufacturer:	Verizon Wireless
Classification Name:	Radiofrequency Physiological Signal Transmitter and Receiver
Common/Usual Name:	Telemedicine System
Regulation Number:	870.2910
Product Codes:	DRG
Subsequent Product Codes:	DXN, NBW, FRW
Classification:	Class II

Entra Health systems has determined that the MyHealthPoint TeleHealth Manager is substantially equivalent to the performance of the three mention predicate devices. The differences between these systems are incidental and not significant. The devices use a similar technological characteristics and principles. Substantial Equivalence section in this submission (Tab 11) explains more on the similarities and equivalence.

Entra Health Systems LLC
3111 Camino del Rio North
Suite 101
San Diego, CA 92108
Main 877 458 2646
Fax 619 584 4504

M. Technological Characteristics

The MyHealthPoint TeleHealth Manager is a software platform for the collection and display of biometric data, from primarily supported patient monitoring devices, to the patient, caregiver and clinician. It is used with in combination with a variety of FDA cleared external bio-metric measuring devices included in the table that follows. Technological characteristics of our device compared to each predicate is shown on the following tables and in the Substantial Equivalence (Tab 11).

M1.DEVICES

Vital Signs/ Product Code	Measurement of Submitted Device (MyHealthPoint)	Vital Signs Equipment Manufacturers/Models (510k)	Predicate #1 Vignet Inc.	Predicate #2 Honeywell HomMed	Predicate #3 Verizon Wireless
Glucose (NBW)	Blood glucose (mg/dl or mmol/L)	Entra Health Systems, MGH-BT1, K081703	Substantially Equivalent	Substantially Equivalent	Substantially Equivalent
Weight (FRI)	Weight Scale (lbs. or Kgs.)/ Body Composition	AnD, UC-321PBT	Substantially Equivalent	Substantially Equivalent	Substantially Equivalent
		Omron, HBF-206IT			
		Fora Weight Scale, W310b			
		Withings Wi-Fi Scale, WS-50			
Pulse Oximetry (DQA)	Pulse Rate and Oxygen Saturation	Nonin, 9560BT, K09336	Substantially Equivalent	Substantially Equivalent	Substantially Equivalent
Blood Pressure (DXN)	Blood pressure ((Systolic (mmHg), Diastolic (mmHg))	AnD, UA-767PBT, K043217	Substantially Equivalent	Substantially Equivalent	Substantially Equivalent
		Omron BP Monitor, BP792IT, K131742			
		Fora BP Monitor, P20b, K092106			
Pedometer (Activity)	Steps, Calories, Sleep	Fitbit, Flexx, Zip, One, Force	Substantially Equivalent	Does not track activity.	Does not track activity.
		BodyMedia, Link, Core			
ECG (DSI,DRX, DPS)	Heart Rate, Respiration	Zephyr , Bioharness 3.1 9607.0090, K113045	Does not have ECG	Substantially Equivalent	Does not have ECG
Thermometer (FLL)	Body Temperature (Celsius or Fahrenheit)	For a, IR20b, K090395	Substantially Equivalent	Substantially Equivalent	Substantially Equivalent
Transfer of Data (OUG)	Medical Device Data System	Qualcomm 2Net, 65-KA123	Substantially Equivalent	Substantially Equivalent	Substantially Equivalent
Medication Reminder (NXB)	Member has the optional ability to add medications or products they are using with a reminder sent by SMS or email.	Built into MyHealthPoint by Entra Health Systems.	Does not have medication reminder.	Substantially Equivalent	Does not have medication reminder.

Entra Health Systems

Entra Health Systems LLC
3111 Camino del Rio North
Suite 101
San Diego, CA 92108
Main 877 458 2646
Fax 619 584 4504

M2.FEATURES

Feature	Submitted Device (MyHealthPoint)	Predicate #1 Vignet Inc.	Predicate #2 Honeywell HomMed	Predicate #3 Verizon Wireless
Intended Use	Home use, wireless collection of data; Remote data access	Substantially Equivalent	Substantially Equivalent	Substantially Equivalent
Indication for Use (Ref: Tab 4)	Remote health management	Substantially Equivalent	Substantially Equivalent	Substantially Equivalent
System description	Software, wireless, reporting and charts, messaging, targets and alerts	Substantially Equivalent	Substantially Equivalent	Substantially Equivalent
Feature	**Submitted Device (MyHealthPoint)**	**Predicate #1 Vignet Inc.**	**Predicate #2 Honeywell HomMed**	**Predicate #3 Verizon Wireless**
Data Collection software	Proprietary Software	Substantially Equivalent	Substantially Equivalent	Substantially Equivalent
Types of home use devices interfaced	FDA cleared home devices: Glucose, Blood pressure, weight/body composition, pulse oximeter, thermometer, ECG, activity, medication reminder	Substantially Equivalent	Substantially Equivalent	Substantially Equivalent
Data Capture method (connectivity)	Wireless, cellular, server to server, client to server.	Substantially Equivalent	Substantially Equivalent	Substantially Equivalent
Power source	Smart device battery, plug for MDDS	Substantially Equivalent	Substantially Equivalent	Substantially Equivalent
Display	Computer, smart phone	Substantially Equivalent	Substantially Equivalent	Substantially Equivalent
Messaging	Secure messages, SMS messaging, motivational, reminders, on line graphical reports and charts, personal progress indicators	Substantially Equivalent	Substantially Equivalent	Substantially Equivalent
Configuration of personal wellness regimen	Configures patient alert settings set by clinician. Messaging.	Substantially Equivalent	Substantially Equivalent	Substantially Equivalent

N. Performance (non-clinical) data

The MyHealthPoint TeleHealth Manager is a software application, therefore no electrical safety or electromagnetic testing was required. After extensive bench testing to performance requirements and criteria established in accordance with application of EN14971 risk analysis,

Entra Health Systems

Entra Health Systems LLC
3111 Camino del Rio North
Suite 101
San Diego, CA 92108
Main 877 458 2646
Fax 619 584 4504

no new issues of safety, performance, technology or intended use were identified. Testing conducted to demonstrate software validation and substantial equivalence included:

- Verification testing that product meets product performance and functional specifications.
- Verification that biometric data submitted by personal home-use devices are captured (wirelessly or manually), transmitted and stored properly to maintain data integrity (e.g. no loss of data or corruption)
- User performance testing to demonstrate adequate instructional utility of the User Manual.

Therefore the MyHealthPoint TeleHealth Manager is concluded to be substantially equivalent to the identified predicates.

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

April 14, 2014

Entra Health Systems
Richard Strobridge
3111 Camino Del Rio North
Suite 101
San Diego, CA 92108 US

Re: K132930
Trade/Device Name: MyHealthPoint TeleHealth Manager
Regulation Number: 21 CFR 870.2910
Regulation Name: Telemedicine System
Regulatory Class: Class II
Product Code: DRG, JQP, DXN, DQA, FLL, DPS, DRX, NXB, FRI, OUG
Dated: March 15, 2014
Received: March 21, 2014

Dear Richard Strobridge:

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

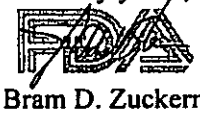
found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,



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

Enclosure

Entra Health Systems

Entra Health Systems LLC
3111 Camino del Rio North
Suite 101
San Diego, CA 92108
Main 877 458 2646
Fax 619 584 4504

Indications for Use

510(k) Number (if known): K132930

Device Name: MyHealthPoint Telehealth Manager

Indications for Use

The MyHealthPoint Telehealth Manager is an accessory software that wirelessly collects, records and transmits biometric data (including glucose, blood pressure, weight, body composition, activity, body temperature, ECG and pulse oximeter readings) from a variety of supported home-monitoring devices as well as supporting manual uploading of data. The MyHealthPoint application uses the same data repository platform that is already cleared, MyGlucoHealth Software System (K081703).

MyHealthPoint TeleHealth Manager is intended to be used by patients in non-clinical settings (e.g. home) to collect, record and transmit their biometric data to a remote secure server. Stored data is accessible by healthcare professionals and caregivers for analysis, messaging and intervention using standard digital communication technologies and protocols. Patients may also view the data to assist in self-management of their specific health condition. The MyHealthPoint Telehealth Manager is intended to be used in combination with a variety of external vital sign devices.

The MyHealthPoint Telehealth Manager is intended to be used by patients identified by their healthcare organization that would benefit from remote monitoring. It is not intended as a replacement of the oversight of healthcare professionals nor does it provide "real-time" or emergency monitoring. It does not measure, interpret or make any decisions on the data that it conveys.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

FDA Date: 2014.04.14 16:08:59-04'00'