510(k) Summary

(in accordance with 21 CFR 807.92)

JUL 16 2012

1. Applicant Information

Applicant:	Vignet Corporation 1616 Anderson Road McLean, VA 22102
Contact Person:	Carlos Gonzalez Tel: 925-209-6605 Fax: 425-940-2417 Email: cgonz1950@gmail.com

Date Prepared:	November 9, 2011

2. Device Name and Classification

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,
Classification:	Class II

3. Predicate Devices

3.1 The Vignet TeleHealth Manager device is substantially equivalent to the following FDA cleared predicate device:

510(k) Number:	K092635
Proprietary Name:	Alcatel-Lucent TeleHealth Manager
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
Classification:	Class II
SE with respect to:	Indications for use, performance and technological characteristics

3.2 The Vignet TeleHealth Manager is used with in combination with a variety of cleared external bio-metric measuring devices including those identified in the table that follows. Corresponding Predicate devices are identified in the table that follows:

Vital Signs Equipment	Physiological information	Vital Signs Equipment Manufacturers/Models (510k)	Predicate TeleHealth Devices (510k)
Blood pressure	Systolic (mmHg), Diastolic (mmHg), Pulse (BPM)	A&D Engineering, Inc. / Model UA-767PBT (K043217) A&D Engineering, Inc. / Model UA-851-PBT Fora Care, Inc. – Taidoc Technology Corporation / Model TD-3250C (K110044)	Alcatel-Lucent TeleHealth Manager (K092635) Avid Care (K011779) Carematix (K040966)
Weight	Weight (lbs. or Kgs.)	A&D Engineering, Inc. / Model UC-321PBT Omron Weight Scale / Model HBF-206IT	Class 1 device does not require predicate
Blood glucose	Glucose (mg/dl or mmol/L)	Entra Health Systems, Ltd. / Model MGH-BT1 (K081703) Fora Care, Inc. – Taidoc Technology Corporation / Model TD-3250C (K110044)	Alcatel-Lucent TeleHealth Manager (K092635) Avid Care (K011779) Carematix (K040966)
Oxygen Saturation	SpO2 (%), Pulse Rate (BPM)	Nonin Medical, Inc. / Model 9560 (K081285)	Avid Care (K011779)
Pedometer	Steps (count), Distance (miles), Time (hours)	Omron Healthcare, Inc. / Model HJ-721IT	Class 1 device does not require predicate
Temperature	Temperature (Fahrenheit or Celsius)	Fora Care, Inc. - Taidoc Technology Corporation / Model IR20b (K090395)	Carematix (K040966)
Peak flow	Peak flow (FEV1, and PEF)	Vitalograph Ltd. / Model 4000 series ASMA-1 (K073155)	Avid Care (K011779) Carematix (K040966)

4. Device Description:

The Vignet TeleHealth Manager is a software system that collects patient physiological data such as blood pressure and blood sugar levels for transmission to a secure central storage server which can be accessed by health care professionals for analysis and intervention using standard digital communication technologies and protocols. This data is also available to the patient for viewing purposes and as an aid in maintaining wellness regimens.

5. Intended use:

The Vignet TeleHealth Manager is an accessory software application that is intended to be used by patients in non-clincal settings (e.g. home), to collect, record and transmit their physiological information to a remote secure server. Stored data is accessible by healthcare professionals for analysis and intervention using standard digital communication technologies and protocols.

The Vignet TeleHealth Manager does not measure, interpret or make any decisions on the data that it conveys. It is not intended as a replacement for the oversight of healthcare professionals nor does it provide "real-time" or emergency monitoring.

6. Performance (non-clinical) data

The Vignet 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, no new issues of safety, performance, technology or intended use were identified.

Therefore the Vignet 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 Room –WO66-G609
Silver Spring, MD 20993-0002

JUL 16 2012

Vignet, Inc.
c/o Mr. Carlos Gonzalez
7833 Knollbrook Dr.
Pleasanton, CA 94588

Re: K113446
Trade Name: Vignet Telehealth Manager
Regulation Number: 21.CFR.892.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter and Receiver
Regulatory Class: Class II (two)
Product Codes: DRG, DXN, NBW
Dated: June 26, 2012
Received: June 28, 2012

Dear Mr. Gonzalez:

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.

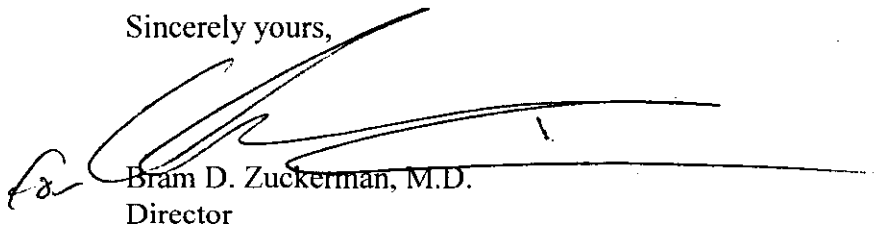
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of 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,



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

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: _Vignet Telehealth Manager

Indications for Use:

The Vignet TeleHealth Manager is an accessory software application that is intended to be used by patients in non-clinical settings (e.g. home), to collect, record and transmit their physiological information to a remote secure server. Stored data is accessible by healthcare professionals for analysis and intervention using standard digital communication technologies and protocols. The Vignet Telehealth Manager is intended to be used in combination with a variety of external vital sign devices.

The Vignet TeleHealth Manager does not measure, interpret or make any decisions on the data that it conveys. It is not intended as a replacement for the oversight of healthcare professionals nor does it provide "real-time" or emergency monitoring.

Prescription Use _____ (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)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K 113446