DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 28, 2017

United Health Group Inc.
Donald Matthews
Associate Director Quality and Regulatory
1100 King Street, Building 6, Suite 300
Rye Brook, New York 10573

Re: K171406
Trade/Device Name: Optum TeleHealth Application
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter And Receiver
Regulatory Class: Class II
Product Code: DRG, DXN, DQA
Dated: July 26, 2017
Received: July 27, 2017

Dear Donald Matthews:

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,

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*

K171406

Device Name

Optum TeleHealth Application

Indications for Use *(Describe)*

The Optum TeleHealth Application is a software application designed to retrospectively monitor vital signs. The following vital signs are collected: noninvasive blood pressure, pulse oximetry, pulse rate, weight, temperature, and blood glucose. The Optum TeleHealth Application collects, displays, and transmits vital sign measurements captured from commercially available FDA cleared medical devices designed for home use, or via manual input by the patient. Collected measurement data from the Optum TeleHealth Application can be transmitted via a secure communication mechanism to a central health data repository. Data can be viewed and analyzed via the Optum TeleHealth Web Application.

The Optum TeleHealth Application is not intended for emergency use or real-time monitoring.

The client application is available in three configurations:
- stand-alone application for both Android and iOS operating systems
- pre-loaded on an Android tablet

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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"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

Manufacturer Name	OptumHealth Care Solutions, Inc.
Address	1100 King Street Bulding 6, Suite 300 Rye Brook, NY 10573
Contact Name	Donald J. Matthews
Title	Associate Director Quality and Regulatory
Phone Number	914-933-4715
Fax Number	914-933-4704
Date Prepared	25 April 2017
Device Proprietary Name	Optum TeleHealth Application
Device Common or Usual Name	TeleHealth Application
Classification Name	Transmitters and Receivers, Physiological Signal, Radiofrequency
Classification Code	DRG
Regulation Number	870.2910

Predicate Devices:
Substantial equivalence is claimed to the following devices in terms of design, technological characteristics, and intended use.

Name of Device	**Manufacturer**	**510(k) Number**
Optum TeleHealth Application	OptumHealth Care Solutions, Inc.	K130971

Description of the Device
The Optum TeleHealth Application is client/server software application which collects and transmits patient vital signs, and physiological data for review, and analysis by clinicians. The software consists of a web based application for clinician use, the client application for member use, and web services. Standard data communication protocols are used. The server hosts the web based application for user management, and patient information and care management. The client application is designed to work with Android devices (OS 4.0 and higher) and Apple devices (iOS 9 and higher), and allows for data input from external biometric measuring devices, review of clinician advice, response to clinician questions, and viewing of graphed data.

The client application is available in two configurations:

- stand-alone application for both Android and iOS operating systems
- pre-loaded on an Android tablet

The device is used in combination with various Class I 510(k) exempt devices and FDA cleared biometric measuring devices, including, but not limited to:

- A&D Medical, UA-767PBT Digital Blood Pressure Monitor (K043217)

- A&D Engineering Inc., UC-321PBT Weight Scale (510(k) exempt)
- TaiDoc Technology Corporation, Fora W310 Weight Scale (510(k) exempt)
- TaiDoc Technology Corporation, Fora IR20b Ear Thermometer (K090395)
- TaiDoc Technology Corporation, Fora P20 Blood Pressure Monitor (K092106)
- Nonin Medical Inc Onyx II Model 9560 Finger Pulse Oximeter (K081285)

Intended Use/Indications for Use

The Optum TeleHealth Application is a software application designed to retrospectively monitor vital signs. The following vital signs are collected: noninvasive blood pressure, pulse oximetry, pulse rate, weight, temperature, and blood glucose. The Optum TeleHealth Application collects, displays, and transmits vital sign measurements captured from commercially available FDA cleared medical devices designed for home use, or via manual input by the patient. Collected measurement data from the Optum TeleHealth Application can be transmitted via a secure communication mechanism to a central health data repository. Data can be viewed and analyzed via the Optum TeleHealth Web Application.

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Technological Characteristics

The client application obtains data via manual data input, or will automatically retrieve stored data from the assigned external biometric measuring devices via Bluetooth communication. Data is transmitted to the server over the internet using standard communication protocols. The client application connects to the server to synchronize with clinician updates via a secure connection.

Pre-Clinical Testing

Bench testing, including software validation, was performed to ensure that the product works as intended.

Conclusion

The Optum TeleHealth Application is substantially equivalent to the predicate devices identified above in terms of design, technological characteristics, and intended use. Results of bench testing show that the product is safe, and effective for use.