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 27, 2015

Proteus Digital Health, Inc.
Jafar Shenasa
Head, Regulatory Affairs
2600 Bridge Parkway, Suite 101
Redwood City, California 94065

Re: K150494
Trade/Device Name: Proteus Digital Health Feedback Device
Regulation Number: 21 CFR 880.6305
Regulation Name: Ingestible Event Marker
Regulatory Class: Class II
Product Code: OZW, DXH
Dated: May 22, 2015
Received: May 28, 2015

Dear Jafar Shenasa:

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,

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

Enclosure

Indications for Use Statement

510(k) Number (if known)

Device Name Proteus® Digital Health Feedback Device

Indications for Use

The Proteus® Digital Health Feedback Device consists of a miniaturized, wearable sensor for ambulatory recording of physiological and behavioral metrics such as heart rate, activity, body angle relative to gravity (body position), and time-stamped patient-logged events, including events signaled by the co-incidence with, or co-ingestion with, the ingestible sensor accessory. When the ingestible sensor is ingested, the Proteus Digital Health Feedback Device is intended to log, track and trend intake times. When co-ingested with medication, the tracking and trending of intake times may be used as an aid to measure medication adherence. The Proteus Digital Health Feedback Device may be used in any instance where quantifiable analysis of event-associated physiological and behavioral metrics is desirable, and enables unattended data collection for clinical and research applications.

Prescription Use __X__ (Per 21 CFR 801.109) OR Over-the-Counter Use _____

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

proteus
DIGITAL HEALTH

510(k) Summary

Submitted by:	Proteus Digital Health Inc.
Address:	2600 Bridge Parkway, Suite 101 Redwood City, CA, 94065
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Contact Name:	Arezou Azar, PhD aazar@proteus.com

Date Submitted:	May22, 2015

Name of Device

Trade name:	Proteus® Digital Health Feedback Device
Common name:	Ingestible Event Marker
Classification name:	Ingestible Event Marker (21 CFR 880.6305)
Product Code:	OZW
Subsequent Codes:	DXH

Predicate Device

- Proteus® Patch Including Ingestible Sensor (K133263)

General Device Description

The Proteus Digital Health Feedback Device consists of a wearable sensor, an ingestible sensor, and a software application.

The Proteus wearable sensor is a body-worn sensor that collects physiological and behavioral metrics such as heart rate, activity, body angle relative to gravity (body position), skin temperature, and time-stamped user-logged events signaled by the co-incidence with, or co-ingestion with, the Proteus ingestible sensor. The display application of the Proteus Digital Health Feedback Device may be used to analyze circadian rhythms and patterns.

The ingestible sensor is embedded inside an inactive tablet (the Proteus Pill or sensor-enabled pill) for ease of handling and swallowing. After the ingestible sensor reaches the stomach, it activates and communicates its presence with a unique identifier to the wearable sensor. When the ingestible sensor is co-ingested with medication, the Proteus device is intended to log, track, and trend medicine intake times as an aid to measure medication adherence.

The software application receives the data from the wearable sensor for further processing and analysis of the physiological and behavioral metrics. The processed data is then sent to the user interface (UI) for display as well as to Proteus databases for storage and sharing.

Intended Use

The Proteus® Digital Health Feedback Device consists of a miniaturized, wearable sensor for ambulatory recording of physiological and behavioral metrics such as heart rate, activity, body angle relative to gravity (body position), and time-stamped patient-logged events, including events signaled by the co-incidence with, or co-ingestion with, the ingestible sensor accessory. When the ingestible sensor is ingested, the Proteus Digital Health Feedback Device is intended to log, track and trend intake times. When co-ingested with medication, the tracking and trending of intake times may be used as an aid to measure medication adherence. The Proteus Digital Health Feedback Device may be used in any instance where quantifiable analysis of event-associated physiological and behavioral metrics is desirable, and enables unattended data collection for clinical and research applications.

Physical Characteristics

Parameter	Values		
	The Wearable Sensor		
	One Piece		Two Piece
Shape	Ovoid		Rectangular
Size	102mm x 60mm x 9.8mm	102mm x 60mm x 6.3mm	98mm x 42mm x 11mm
Weight	11 grams	10 grams	16 grams
Battery Type	Lithium Manganese (LiMn) Coin Cell	Lithium Manganese (LiMn) Coin Cell	Lithium Manganese (LiMn) Coin Cell
Moisture Susceptibility	Water-Resistant	Water-Resistant	Water-Resistant
Memory	4 MB	16 MB	16 MB
Storage Temperature	Room Temperature	Room Temperature	Room Temperature
Relative Humidity	Ambient	Ambient	Ambient
	The Pill		
Shape	Round		
Size	6.5mm x 2.0mm		
Weight	80mg		

Technological Characteristics

The technological characteristics of the current device are identical to the predicate device.

Parameter	Sensor Technology	Method
Heart rate	Biopotential low-frequency amplifier	Digitized R wave
Activity	Accelerometer	Digitized accelerometer output
Body Angle	Accelerometer	Double integration of accelerometer output
Skin Temperature	Thermistor	Digitized voltage from small auxiliary current
Manual Event Logging	Patient activated button	Digital pulse
Inter-Electrode Impedance	Biopotential high-frequency amplifier	Digitized impedance from small auxiliary current
Ingestible Event Marker	Bio-galvanically powered ingestible circuit	Volume conduction communication

Summary of Non-Clinical Performance Data

The three-axis accelerometer provided motion and angle relative to gravity (body position) data and was validated against a known acceleration applied against each of its three axes.

The biopotential low-frequency amplifier was used to quantify heart rate by measuring R-wave frequency based upon a proprietary algorithm, tested using selected guidelines set forth in the ANSI/AAMI EC 13 standard.

The thermistor provided local skin environment temperature. A small current was applied across the thermistor, and the difference in voltage was quantifed and compared to a reference resistor.

The ingestible sensor was tested for activation time and lifetime after activation.

Summary of Clinical Performance Data

No additional clinical data were required to confirm substantial equivalence to predicate devices.

Conclusion

Based on technological characteristics, risk evaluation, and design verification of the Proteus Digital Health Feedback Device, Proteus Digital Health believes that the product is safe and effective, and is substantially equivalent to its predicate device.