



JUN 23 2013

K131524

P1/4

### 510(k) Summary

Submitted by: Proteus Digital Health Inc.  
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Date Submitted: May 24, 2013

#### Name of Device

Trade name: Proteus® Patch Including Ingestible Sensor  
Common name: Ingestible Event Marker  
Classification name: Ingestible Event Marker (21 CFR 880.6305, Product Code OZW, DXH)

#### Unmodified Device

- Proteus® Patch Including Ingestible Sensor (K131009)

#### General Device Description

The Proteus Patch is a body-worn sensor that collects physiological and behavioral metrics such as heart rate, activity, body angle relative to gravity, and time-stamped user-logged events generated by swallowing the Proteus Ingestible Sensor. The Ingestible Sensor is embedded inside an inactive tablet (the Pill) for ease of handling and swallowing. Once the Ingestible Sensor reaches the stomach, it activates and communicates its presence and unique identifier to the Patch. The Patch stores and wirelessly sends the physiological, behavioral, event, and ingestion data to a general computing device for display.

**Intended Use**

The Proteus<sup>®</sup> Patch is a miniaturized, wearable data-logger for ambulatory recording of physiological and behavioral metrics such as heart rate, activity, body angle relative to gravity, and time-stamped, patient-logged events, including events signaled by swallowing the Ingestible Sensor accessory. The Proteus Patch enables unattended data collection for clinical and research applications. The Proteus Patch may be used in any instance where quantifiable analysis of event-associated physiological and behavioral metrics is desirable.

**Physical Characteristics**

<b>Parameter</b>	<b>Value</b>
<b>The Patch</b>	
<b>Shape</b>	One-piece: ovoid
<b>Size</b>	102mm x 56mm x 10mm
<b>Weight</b>	11g
<b>Battery type</b>	Lithium Manganese (LiMn) Coin Cell
<b>Moisture susceptibility</b>	Water-resistant
<b>Memory</b>	4 MB
<b>Storage temperature</b>	Room Temperature
<b>Relative humidity</b>	Ambient
<b>The Pill</b>	
<b>Shape</b>	Round
<b>Size</b>	6.5mm x 2.0mm
<b>Weight</b>	80mg

**Technological Characteristics**

<b>Parameter</b>	<b>Sensor Technology</b>	<b>Method</b>
<b>Heart rate</b>	Biopotential low-frequency amplifier	Digitized R wave
<b>Activity</b>	Accelerometer	Digitized accelerometer output
<b>Body angle</b>	Accelerometer	Double integration of accelerometer output
<b>Manual event logging</b>	Patient activated button	Digital pulse
<b>Inter-electrode impedance</b>	Biopotential high-frequency amplifier	Digitized impedance from small auxiliary current
<b>Ingestible Event Marker</b>	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 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 modified Hamilton-Tompkins algorithm, tested using guidelines set forth in the ANSI/AAMI EC 13 standard.

The Ingestion 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 device.

**Conclusion**

K131524

P4/4

Based on technological characteristics, risk evaluation, and design verification of the Proteus Patch Including Ingestible Sensor, Proteus Digital Health believes that the product is safe and effective, and is substantially equivalent to predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

June 23, 2013

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-002

Proteus Digital Health, Inc.  
Mr. Zahedeh Hatamkhany  
Cmc Regulatory-Combination Products  
2600 Bridge Parkway, Suite 101  
Redwood City, CA 94065 US

Re: K131524  
Trade/Device Name: Proteus Patch including Ingestible Sensor  
Regulation Number: 21 CFR 880.6305  
Regulation Name: Ingestible Event Marker  
Regulatory Class: Class II  
Product Code: OZW, DXH  
Dated: May 24, 2013  
Received: May 28, 2013

Dear Mr. Zahedeh Hatamkhany:

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 (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,

**Bram D. Zuckerman -S**

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

K131524

## Indications for Use Statement

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

**Device Name** Proteus<sup>®</sup> Patch including Ingestible Sensor

**Indications for Use** The Proteus<sup>®</sup> Patch is a miniaturized, wearable data-logger for ambulatory recording of physiological and behavioral metrics such as heart rate, activity, body angle relative to gravity, and time-stamped, patient-logged events, including events signaled by swallowing the Ingestible Sensor accessory. The Proteus Patch enables unattended data collection for clinical and research applications. The Proteus Patch may be used in any instance where quantifiable analysis of event-associated physiological and behavioral metrics is desirable.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

**Bram D. Zuckerman -S**  
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