510(k) Summary

Submitted by: Proteus Digital Health Inc.
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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)

Unmodified Devices
- Proteus Personal Monitor (K113070)
- Raisin™ Personal Monitor (K093976)

General Device Description
Like the Proteus Personal Monitor (K113070), the Proteus Patch is a body-worn sensor that collects physiological and behavioral metrics including heart rate, activity, body angle, 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 physiologic, event, accelerometry, and Ingestible Sensor data to a general computing device for display.
**Intended Use**

The Proteus Patch, also called the 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**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>The Patch</strong></td>
<td></td>
</tr>
<tr>
<td>Shape</td>
<td>One-piece: ovoid</td>
</tr>
<tr>
<td>Size</td>
<td>101mm x 53mm x 13mm</td>
</tr>
<tr>
<td>Weight</td>
<td>16g</td>
</tr>
<tr>
<td>Battery type</td>
<td>Lithium Polymer</td>
</tr>
<tr>
<td>Moisture susceptibility</td>
<td>Waterproof</td>
</tr>
<tr>
<td>Memory</td>
<td>4 MB</td>
</tr>
<tr>
<td>Storage temperature</td>
<td>Room Temperature</td>
</tr>
<tr>
<td>Relative humidity</td>
<td>Ambient</td>
</tr>
<tr>
<td><strong>Ingestible Sensor</strong></td>
<td></td>
</tr>
<tr>
<td>Shape</td>
<td>Round</td>
</tr>
<tr>
<td>Size</td>
<td>6.5mm x 2.0mm</td>
</tr>
<tr>
<td>Weight</td>
<td>80mg</td>
</tr>
</tbody>
</table>
Technological Characteristics

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Sensor Technology</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart rate</td>
<td>Biopotential low-frequency amplifier</td>
<td>Digitized R wave</td>
</tr>
<tr>
<td>Activity</td>
<td>Accelerometer</td>
<td>Digitized accelerometer output</td>
</tr>
<tr>
<td>Body angle</td>
<td>Accelerometer</td>
<td>Double integration of accelerometer output</td>
</tr>
<tr>
<td>Manual event logging</td>
<td>Patient activated button</td>
<td>Digital pulse</td>
</tr>
<tr>
<td>Inter-electrode impedance</td>
<td>Biopotential high-frequency amplifier</td>
<td>Digitized impedance from small auxiliary current</td>
</tr>
<tr>
<td>Ingestible Event Marker</td>
<td>Bio-galvanically powered ingestible circuit</td>
<td>Volume conduction communication</td>
</tr>
</tbody>
</table>

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 devices.
Conclusion

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 devices.
Dear Mr. 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 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,

Owen D. Faris - S

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

510(k) Number
(if known)  K131009

Device Name  Proteus® Patch including Ingestible Sensor

Indications for Use  The Proteus® Patch, also called the 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 heart rate, activity, and body position is desirable.

Prescription Use  X  OR  Over-the-Counter Use  ____
(Per 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Owen P. Faris -S
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