



Food and Drug Administration
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Proteus Biomedical, Inc.
c/o Mr. Jafar Shenasa
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2600 Bridge Parkway, Suite 101
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JUL 20 2012

Re: K113070
Proteus Personal Monitor including Ingestion Event Marker
Evaluation of Automatic Class III Designation
Regulation Number: 21 CFR 880.6305
Regulation Name: Ingestible Event Marker
Regulatory Classification: Class II
Product Code: OZW
Dated: May 9, 2012
Received: May 14, 2012

Dear Mr. Shenasa:

This letter corrects our previous letter dated July 10, 2012.

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your Evaluation of Automatic Class III Designation Petition (de novo) for classification of the Proteus Personal Monitor including Ingestion Event Marker. The Proteus Personal Monitor including Ingestion Event Marker is a miniaturized, wearable data-logger for ambulatory recording of heart rate, activity, body angle relative to gravity, and time-stamped, patient-logged events, including events signaled by swallowing the Ingestion Event Marker (IEM) accessory. The Proteus Personal Monitor enables unattended data collection for clinical and research applications. The Proteus Personal Monitor may be used in any instance where quantifiable analysis of event-associated heart rate, activity, and body position is desirable. This device is a prescription device under 21 CFR Part 801.109. FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies the Proteus Personal Monitor including Ingestion Event Marker, and substantially equivalent devices of this generic type, into class II under the generic name, Ingestible Event Marker.

FDA identifies this generic type of device as: Ingestible Event Marker - An ingestible event marker is a prescription device used to record time-stamped, patient-logged events. The ingestible

component links wirelessly through intra-body communication to an external recorder which records the date and time of ingestion as well as the unique serial number of the ingestible device.

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(1)) (the FD&C Act), devices that were not in commercial distribution prior to May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976 (the amendments)), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act (21 U.S.C. 360c(i)), to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and Part 807 of the FDA regulations (21 CFR 807).

Section 513(f)(2) of the FD&C Act provides that any person who submits a premarket notification under section 510(k) for a device may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1), request FDA to classify the device under the criteria set forth in section 513(a)(1). FDA shall, within 60 days of receiving such a request classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** classifying the device type.

In accordance with section 513(f)(1) of the FD&C Act, FDA issued an order on May 7, 2012, automatically classifying the Proteus Personal Monitor including Ingestion Event Marker in class III, because it was not within a type of device which was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, nor which was subsequently reclassified into class I or class II. On May 14, 2012, FDA filed your petition requesting classification of the Proteus Personal Monitor including Ingestion Event Marker into class II. The petition was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Proteus Personal Monitor including Ingestion Event Marker into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

After review of the information submitted in the petition, FDA has determined that the Proteus Personal Monitor including Ingestion Event Marker can be classified in class II with the establishment of special controls when indicated for ambulatory recording of heart rate, activity, body angle relative to gravity, and time-stamped, patient-logged events, including events signaled by swallowing the Ingestion Event Marker (IEM) accessory. The Proteus Personal Monitor is a miniaturized, wearable data-logger for ambulatory recording of heart rate, activity, body angle relative to gravity, and time-stamped, patient-logged events, including events signaled by swallowing

the Ingestion Event Marker (IEM) accessory. The Proteus Personal Monitor enables unattended data collection for clinical and research applications. The Proteus Personal Monitor may be used in any instance where quantifiable analysis of event-associated heart rate, activity, and body position is desirable. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type.

Table - Potential Risks and Mitigations

| Identified Risks | Recommended Mitigation Measures |
|---------------------------------|---|
| Adverse tissue reaction | Biocompatibility Testing Labeling (dose limits) |
| Systemic toxicity | Toxicology Testing Labeling (dose limits) |
| Electromagnetic incompatibility | Electromagnetic Compatibility Testing Wireless Testing Labeling |
| Electrical safety issues | Electrical Safety Testing Labeling |
| Electrical/Mechanical failure | Non-clinical Performance Testing |
| Failure to mark event | Non-clinical Performance Testing Clinical Evaluation |
| Failure to excrete | Animal Testing |
| Usability | Human Factors Testing Labeling |

In addition to the general controls of the FD&C Act, the Ingestible Event Marker is subject to the following special controls: (1) The device must be demonstrated to be biocompatible and non-toxic; (2) Non-clinical, animal and clinical testing must provide a reasonable assurance of safety and effectiveness, including device performance, durability, compatibility, usability (human factors testing), event recording, and proper excretion of the device; (3) Appropriate analysis and non-clinical testing must validate electromagnetic compatibility (EMC) performance, wireless performance, and electrical safety; and (4) Labeling must include a detailed summary of the non-clinical and clinical testing pertinent to use of the device and the maximum number of daily device ingestions. In addition, this is a prescription device and must comply with 21 CFR 801.109.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the

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Ingestible Event Marker they intend to market prior to marketing the device and receive clearance to market from FDA.

A notice announcing this classification order will be published in the **Federal Register**. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the de novo, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact James Cheng at (301) 796-6306.

Sincerely yours,



Jonette Foy, Ph.D.
Deputy Director
for Science and Regulatory Policy
Office of Device Evaluation
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