August 11, 2023

Otsuka America Pharmaceutical, Inc.
Nancy Teague
Senior Director, Global Regulatory Affairs
2440 Research Boulevard
Rockville, Maryland 20850

Re: K223463
Trade/Device Name: Otsuka Digital Feedback Device-RW
Regulation Number: 21 CFR 880.6305
Regulation Name: Ingestible Event Marker
Regulatory Class: Class II
Product Code: OZW
Dated: July 10, 2023
Received: July 10, 2023

Dear Nancy Teague:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Shruti N. Mistry -S

Jennifer Shih Kozen
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223463

Device Name
Otsuka Digital Feedback Device-RW

Indications for Use *(Describe)*
The Otsuka Digital Feedback Device-RW 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 Otsuka Digital Feedback Device-RW 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 Otsuka Digital Feedback Device-RW 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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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

Submitted by:	Otsuka America Pharmaceutical, Inc.
Address:	2440 Research Blvd.
	Rockville, MD 20850
Telephone:	410-353-8778
Contact Name:	Nancy F. Teague
	Senior Director, Global Regulatory Affairs
	nancy.teague@otsuka-us.com
Date Submitted:	18 Nov 2022
Name of Device:	Otsuka Digital Feedback Device-RW
Tradename:	Otsuka Digital Feedback Device-RW
Common Name:	Ingestible Event Marker with wearable patch
Classification Name:	Ingestible Event Marker, 21 CFR 880.6305
Product Code:	OZW
Predicate Device:	Proteus Digital Health Feedback Device, K150494
	Proteus Patch, Proteus Ingestible Sensor, K133263

General Device Description:

The Otsuka Digital Feedback Device-RW consists of three components: a wearable sensor, an ingestible sensor accessory, and software that aggregates, processes and enables display of data collected by the sensors.

The wearable sensor is a body-worn sensor (also called the patch) that collects physiological and behavioral metrics such as heart rate, activity, body angle, and time-stamped patient-logged events, including events signaled by the co-incidence with, or co-ingestion with, the ingestible sensor accessory. The wearable sensor in the Otsuka Digital Feedback Device-RW is a 2-component patch known as the RW2 wearable sensor or RW2 patch.

The ingestible sensor is embedded inside an inactive tablet (the 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 (ID) to the wearable sensor. When the ingestible sensor is co-ingested with medication, the Otsuka Digital Feedback Device-RW is intended to log, track and trend medicine intake times to measure medication adherence.

The software on a general computing device (eg, mobile device) receives the data from the body-worn sensor or patch for further processing and analysis of the behavioral and physiological metrics. The processed data is then sent to the user interface (UI) for display as well as being saved in a local record database for storage.

For purposes of this 510(k), the changes from the predicate device to the device subject of this 510(k) are the wearable sensor and the software for the UI display. The ingestible sensor remains the same from the predicate device.

Indications for Use:

The Otsuka Digital Feedback Device-RW 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 Otsuka Digital Feedback Device-RW is intended to log, track and trend intake times. When co-ingested with medication, the tracking and trending times may be used as an aid to measure medication adherence. The Otsuka Digital Feedback Device-RW 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.

Technological Characteristics:

Product Name	Otsuka Digital Feedback Device-RW with RW2 Patch (Subject Device of this 510(k))	Proteus Digital Health Feedback Device with DW5 Patch	Proteus RW1 Patch Including Ingestible Sensor
510(k) Number	**K223463**	**K150494**	**K133263**
Patch Detection Capability	Improved algorithm from DW5 patch which allows for expanded wear location to either side of the torso.	Algorithm allows for patch to be worn on the left side of the torso	Algorithm allows for patch to be worn on the left side of the torso
Materials/Layer Construction	RW2 uses skin adhesive MED5750A and Hydrogel Axelgaard AG625. Skin contacting materials pass ISO 10993 testing for irritation, cytotoxicity and sensitization, and/or has been used in another 510(k)-cleared product for similar skin contact use.	DW5 uses skin adhesive MED5750A, Hydrogel Covidien RG-63B and a hydrocolloid foam top. All skin contacting materials pass ISO 10993 testing for irritation, cytotoxicity and sensitization	RW1 uses skin adhesive MED5750A and Hydrogel Covidien RG-63B. All skin contacting materials pass ISO 10993 testing for irritation, cytotoxicity and sensitization
Battery Life	7-day battery life	7-day battery life	30-day battery life
Dimension:	Thickness - 8.2 mm Length - 110 mm Width - 53 mm	Thickness - 6.3 mm Length - 102 mm Width - 60 mm	Thickness - 11 mm Length - 97.5 mm Width - 42 mm
Shelf Life	3 years	3 years	1 year
Event Marker	Ingestible event marker	Ingestible event marker	Ingestible event marker
Accelerometer	3-axis accelerometry	3-axis accelerometry	3-axis accelerometry
Hardware (Ingestible Sensor)	Ingestible event marker	Ingestible event marker	Ingestible event marker
Hardware (Wearable Sensor)	Wearable, physiologic sensor; 2-component patch	Wearable, physiologic sensor; 1-component patch	Wearable, physiologic sensor; 2-component patch
Firmware (Wearable Sensor)	Collects data from sensor, performs data processing, stores data until wireless connection is available, sends data to general computing device	Collects data from sensor, performs data processing, stores data until wireless connection is available, sends data to mobile device	Collects data from sensor, performs data processing, stores data until wireless connection is available, sends data to mobile device
Software	Aggregates, processes and enables display of data collected by sensors	Aggregates, processes and displays data collected by sensors	Aggregates, processes and displays data collected by sensors
Data Telemetry	Bluetooth Technology	Bluetooth Technology	Bluetooth Technology
Biocompatibility	ISO 10993 compliant	ISO 10993 compliant	ISO 10993 compliant

Product Name	Otsuka Digital Feedback Device-RW with RW2 Patch (Subject Device of this 510(k))	Proteus Digital Health Feedback Device with DW5 Patch	Proteus RW1 Patch Including Ingestible Sensor
510(k) Number	**K223463**	**K150494**	**K133263**
Electrical Safety/EMC	IEC 60601-1/IEC 60601-1-2 compliant	IEC 60601-1/IEC 60601-1-2 compliant	IEC 60601-1/IEC 60601-1-2 compliant

Abbreviations: EMC = electromagnetic compatibility; TBD = to be determined

Summary of Non-Clinical Performance Data:

Risk evaluations and verification and validation testing were conducted for each feature that differed from the predicate devices, Proteus Digital Health Feedback Device (K150494) and Proteus Patch, Proteus Ingestible Sensor (K133263), to the Otsuka Digital Feedback Device-RW. The results demonstrate that the acceptance criteria for firmware verification, mechanical verification, electrical verification, biocompatibility evaluation, and system verification testing were met.

Summary of Clinical Performance Data:

Clinical studies were conducted to support the expanded wear location of the patch to include the entire front abdomen. However, new clinical studies were not performed to support the changes proposed in this submission.

Conclusion:

Based on the indication for use statement, technological characteristics, risk evaluations, and device verification and validation testing, the Otsuka Digital Feedback Device-RW does not raise new questions of safety or effectiveness and is substantially equivalent to the predicate devices.