June 30, 2025

Otsuka America Pharmaceutical, Inc.
% Nancy Teague
Senior Director, Global Regulatory Affairs
Otsuka Product Development & Commercialization, Inc.
2440 Research Blvd
Rockville, Maryland 20850

Re: K251088
Trade/Device Name: Otsuka Digital Feedback Device
Regulation Number: 21 CFR 880.6305
Regulation Name: Ingestible Event Marker
Regulatory Class: Class II
Product Code: OZW, DXH
Dated: April 3, 2025
Received: April 9, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Jennifer W. Shih -S

Jennifer 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251088

Please provide the device trade name(s).

Otsuka Digital Feedback Device

Please provide your Indications for Use below.

The Otsuka Digital 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 co-incidence with, or co ingestion with, the ingestible sensor accessory. When the ingestible sensor is ingested, the Otsuka Digital 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 Otsuka Digital 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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

12.5 510(k) Summary

Submitted by:	Otsuka America Pharmaceutical, Inc.
Address:	3956 Point Eden Way
	Hayward, CA 94545
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Contact Name:	Nancy F. Teague
	Senior Director, Global Regulatory Affairs
	nancy.teague@otsuka-us.com

Name of Device:	Otsuka Digital Feedback Device
Tradename:	Otsuka Digital Feedback Device
Common Name:	Ingestible Event Marker with wearable patch
Classification Name:	Ingestible Event Marker, 21 CFR 880.6305
Product Code:	OZW

Predicate Device:	Otsuka Digital Feedback Device-RW, K223463

12.5.1 General Device Description

The Otsuka Digital Feedback Device consists of 3 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 in the Otsuka Digital Feedback Device is a body-worn sensor that consists of a single-use patch known as the D-Tect wearable sensor or D-Tect Patch. The D-Tect Patch 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. Note: While the device includes automated heart rate (HR) measurement, it does not provide an ECG waveform recording for display or analysis. The device is not intended to diagnose heart-related conditions and does not include alarms. HR measurement is not intended to be used in alarm system. HR data may not be accurate for patients with pacemakers.

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 to the wearable sensor. When the ingestible sensor is co-ingested with medication, the Otsuka Digital Feedback Device is intended to log, track, and trend medicine intake times to measure medication adherence.

The software on the general computing device receives the data from the wearable sensor for further processing and analysis of metrics. The processed data is then sent to the user interface for display, as well as being saved in a local record database for storage. The software component includes firmware running on the wearable sensor that collects and records the data from the sensors and a software that receives data from the wearable sensor for further analysis, processing, storage, and display to the user.

For purposes of this 510(k), the changes from the predicate device (Otsuka Digital Feedback Device-RW, K223463) to the Otsuka Digital Feedback Device with D-Tect Patch (the device subject of this 510[k]) are the wearable sensor and the software for the user interface. The ingestible sensor remains the same as the predicate device.

12.5.2 Indications for Use

The Otsuka Digital 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 co-incidence with, or co-ingestion with, the ingestible sensor accessory. When the ingestible sensor is ingested, the Otsuka Digital 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 Otsuka Digital 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.

12.5.3 Technological Characteristics and Predicate Comparison

Technical characteristics and predicate comparison are shown in Table 12.5.3-1.

Table 12.5.3-1 Technological Characteristics and Predicate Comparison

	Subject of this 510(k)	**Predicate Device**
Trade Name	**Otsuka Digital Feedback Device**	**Otsuka Digital Feedback Device-RW**
Common Name	**Otsuka Digital Feedback Device (with D-Tect Patch)**	**Otsuka Digital Feedback Device-RW with RW2 Patch**
510(k) Number	**K251088**	**K223463**
Indications for Use	The Otsuka Digital 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 Otsuka Digital 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 Otsuka Digital 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.	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.
Common Name	IEM	IEM
Classification Name	IEM	IEM
Product Code	OZW	OZW
Subsequent Product Codes	DXH	DXH
Event Marker, Co-ingestion with:	IEM	IEM

Table 12.5.3-1 Technological Characteristics and Predicate Comparison		
	Subject of this 510(k)	**Predicate Device**
Trade Name	**Otsuka Digital Feedback Device**	**Otsuka Digital Feedback Device-RW**
Common Name	**Otsuka Digital Feedback Device (with D-Tect Patch)**	**Otsuka Digital Feedback Device-RW with RW2 Patch**
510(k) Number	**K251088**	**K223463**
Temperature Sensor	Thermistor	Thermistor
Accelerometer	3-axis accelerometry	3-axis accelerometry
Hardware (Ingestible Sensor)	Ingestible event marker	Ingestible event marker
Hardware (Wearable Sensor)	Wearable, physiologic sensor (1-component wearable sensor or patch). There is no reuse of this patch. Single Microprocessor Architecture Low noise AFE	Wearable, physiologic sensor (2-component wearable sensor or patch). Dual Microprocessor Architecture Low noise AFE
Wear Location	Front torso left and right sides	Front torso left and right sides
Mechanical (Wearable Sensor) Device dimensions	Smaller, more comfortable design with a curved membrane connecting the 2 electrodes. 6.4 mm 113.2 mm 45.2 mm	 8.2 mm 110 mm 53 mm
Mechanical (Wearable Sensor) Layer Construction	Comparable skin adhesive from the same manufacturer and identical hydrogel material. Skin adhesive MED5741 Hydrogel Axelgaard AG625	 Skin adhesive MED5750A Hydrogel Axelgaard AG625
Firmware (Wearable Sensor)	Collects data from sensor, performs data processing, stores data in the encrypted format 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 general computing device.

Table 12.5.3-1 Technological Characteristics and Predicate Comparison		
	Subject of this 510(k)	**Predicate Device**
Trade Name	**Otsuka Digital Feedback Device**	**Otsuka Digital Feedback Device-RW**
Common Name	**Otsuka Digital Feedback Device (with D-Tect Patch)**	**Otsuka Digital Feedback Device-RW with RW2 Patch**
510(k) Number	**K251088**	**K223463**
Improved Pill Detection Capability	Enhanced low-noise analog front end improves sensitivity of the IEM detection by >50%, increasing the likelihood of detection.	IEM detection with the ability to detect signals with lower (nV) amplitudes.
Improved Step Counting	Improved step metric based on passive fully continuous step counting.	Periodic step counting using raw motion data sampled briefly each minute to estimate steps per minute.
Improved Heart Rate Measurements	Verified against real ECG signals and 100% measurement accuracy for simulated ECG signal.	Verified against simulated ECG signals with >90% measurement accuracy.
Software	Aggregates, decrypts, processes, and enables display of data collected by sensors	Aggregates, processes, and enables display of data collected by sensors
Cybersecurity	Improved cybersecurity and data privacy. Data encrypted while at rest and in flight. Increased security during Bluetooth pairing, over-the-air upgrade with image signatures and rollback protection.	No encryption of data at rest on the patch, with basic Bluetooth pairing security.
Data Telemetry	Bluetooth Technology	Bluetooth Technology
Biocompatibility	ISO 10993 compliant	ISO 10993 compliant
Electrical Safety/EMC	IEC 60601-1/IEC 60601-1-2 compliant	IEC 60601-1/IEC 60601-1-2 compliant

AFE = analog front end; D-Tect = Otsuka Digital Feedback Device body-worn sensor; DW5 = Disposable Wearable 5, earlier generation of wearable sensor (predicate); EMC = electromagnetic compatibility; IEC = International Electrotechnical Commission; IEM = ingestible event marker; ISO = International Organization for Standardization; RW = Reusable Wearable; RW2 = Reusable Wearable 2, earlier generation of wearable sensor (predicate); TBD = to be determined

12.5.4 Summary of Non-Clinical Performance Data

Performance testing was conducted to demonstrate that the patch meets all safety and effectiveness requirements. Testing focused on features that differ from the predicate

device, Otsuka Digital Feedback Device-RW (K223463), as well as comprehensive verification and validation of the complete system.

The testing program successfully demonstrated that acceptance criteria were met for the following performance characteristics:

Biocompatibility

Biocompatibility testing was performed, and the patch has been evaluated and deemed compliant with all the applicable requirements of ISO 10993-23-2021 (Irritation), ISO 10993-5-2009 (Cytotoxicity), and ISO 10993-10-2021 (Sensitization). Based on Annex A of ISO 10993-1, the patch is considered as a surface device with skin (uncompromised) contact and C - Long term contact duration (>30 d).

Shelf Life

Material stability and functionality testing was performed, and the patch has a verified shelf life of 3-years from the date of manufacturing.

Mechanical and Electrical

Formal verification testing was performed to confirm all mechanical and electrical requirements and specifications with passing results.

Examples of the mechanical testing performed include:

LED functionality; on button functionality; structural adhesive and mechanical enclosure integrity; dimensional and physical characteristics; water ingress protection; vibration, impact, push and drop testing, and markings durability.

Examples of electrical testing performed include:

- Static Testing, where conformance with the requirements and specifications is verified by inspection of the hardware design and documentation, such as schematics, BOM, and the hardware assembly.
- Requirement verification testing, to ensure that the design meets all the functional requirements.
- Environmental testing, to ensure functionality over operational, storage, and transportation temperature conditions.

Patient Electrical Safety and Electromagnetic Compatibility (EMC) Testing

- **Electrical Safety Standards Compliance**

The patch has been evaluated and deemed compliant with all the applicable requirements of the following standards:

- **IEC 60601-1: 2005 + A1:2012 + A2:2020**
- **IEC 60601-1-2: 2014 + A1:2020**
- **IEC 60601-1-11: 2015 + A1:2020**
- **IEC 60601-1-6: 2010 + A1:2013 + A2:2020**

- **Device Safety Profile:**

Degree of Protection:	Type BF applied Part
Protection against Electrical Shock:	Internally powered medical equipment
Mode of Operation:	Continuous
Enclosure degree of Ingress Protection:	IP27 (waterproof to 1m – 3.3 feet)
Essential Performance:	This device has no essential performance (if the device is compromised, there is no unacceptable risk to the user)
Use Environment:	Home Healthcare environment

- **EMC Testing**

The patch meets the following EMC classification:

- RF Emissions: CISPR 11 Group 1
- RF Environment: CISPR 11 Class B
- RF Interference Immunity: IEC 61000-4-3 Level 3
- ESD Discharge Immunity: IEC 61000-4-2 Level 4

The patch, mobile device, and software underwent electrical safety and EMC evaluation. The complete system meets the requirements of IEC 60601-1 safety standards and complies to both the third and fourth edition versions of the IEC 60601-1-2 EMC standard.

Device software

The embedded firmware and mobile application software were developed, verified, and validated in accordance with:

- FDA guidance “Content of Premarket Submissions for Device Software Functions” (2023)

- IEC 62304: Medical Device Software – Software Life Cycle Processes
- ISO 14971: Application of Risk Management to Medical Devices

All identified software requirements were tested and successfully passed. No anomalies remain that would impact performance, safety, or effectiveness of the device.

Embedded Firmware

The embedded firmware controls core device functions including signal acquisition, processing, encrypted data storage, wireless communication, and power management. Verification and validation included functional testing, performance testing, simulated-use and bench testing under representative and boundary conditions.

All firmware testing was completed on the final hardware design. Test results met predefined acceptance criteria, and no unresolved issues remain.

Mobile Application Software

The mobile application enables secure user interaction and data exchange with the patch. Functional verification and validation included testing for user authentication, access control, secure Bluetooth pairing, connection stability, and data integrity. It also covered time synchronization, encryption and cross-platform compatibility on supported iOS and Android versions and simulated-use scenarios to confirm usability and responsiveness.

Test results met predefined acceptance criteria, and no unresolved issues remain.

Cybersecurity

Cybersecurity measures have been verified to ensure compliance with Section 524B of the FD&C Act and the FDA guidance "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions" (issued September 27, 2023). In addition, applicable security tests were conducted in accordance with AAMI/Underwriters Laboratories (UL) 2900-1:2017, Clauses 13 to 19. The device incorporates security controls designed to protect patient safety, maintain data integrity, and prevent unauthorized access.

Cybersecurity risk management activities were performed in alignment with the above FDA guidance, as well as to the relevant standards like AAMI TIR-57:2016/2023, and NIST SP 800-30 including ISO 14971:2019 (Medical devices - Application of Risk

Management to Medical Devices) for risk management, ensuring a risk-based, comprehensive approach to identifying and mitigating potential cybersecurity threats.

Third party security and penetration testing were also completed, and no critical vulnerabilities were found.

12.5.5 Summary of Clinical Performance Data

A noninterventional validation study was conducted in healthy subjects with the primary objective to evaluate wear duration, a specification of the wearable patch, while other specifications were also evaluated (e.g., wear comfort and safety assessment). A total of 55 subjects were tested at 1 site in the United States. All 55 subjects were analyzed for safety, and 51 subjects completed the study. Subjects were asked to wear 2 patches, one at a time, for up to 2 consecutive wear periods that each consisted of up to 7 days. Patches were placed on the torso where the skin was free of hair, clean, dry, and healthy, and the second patch was placed in a location that did not overlap the same area of skin as the first patch.

Efficacy results for wear duration showed a minimum of 79.0% adherence (with 95% confidence using a Wilson Score Interval) for a minimum of 5 days, which passed the 50% patch adherence specification (ie, adherence for ≥ 5 days in ≥ 50% of subjects). Furthermore, a minimum of 61.5% adherence (with 95% confidence) was observed for a minimum of 7 days. Overall, efficacy findings demonstrated that the tradeoff of patch flexibility and adhesive area was successful.

Comfort results showed an average comfort rating of 4.7 (very comfortable) on a scale of 1 to 5 with 1 = very uncomfortable and 5 = very comfortable, which passed the >3.5 minimum comfort specification.

Safety assessment resulting in an AE of Grade 1 (minimal erythema, barely perceptible), or Grade 2 (definite erythema, readily visible; minimal edema or minimal papular response) score occurred for 7/55 (12.7%) subjects, with 6/55 (10.9%) experiencing Grade 1 and 2/55 (3.6%) experiencing Grade 2 (considered clinically relevant). All other subjects had skin irritation scores assessed as Grade 0 (no evidence of irritation). The new patch design has a similar safety profile to the predicate device and no new safety concerns have been identified.

12.5.6 Testing to Consensus Standards

The following Standards were used for the development and testing of the patch:

Standards Developing Organization	Designation Number and Edition Date	Standard Title	FDA Recognition Number
AAMI	TIR57:2016	Principles for medical device security – Risk management	13-83
IEC	60601-1 Edition 3.2 2020-08 Consolidated Version	Medical electrical equipment-Part 1 : General requirements for basic safety and essential performance	19-49
IEC	60601-1-6 Edition 3.2 2020-07 Consolidated Version	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	5-132
IEC	60601-1-11 Edition 2.1 2020-07 Consolidated Version	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	19-38
IEC	TR 60601-4-2 Edition 1.0 2016-05	Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems	19-19
IEC	60601-2-27 Edition 3.0 2011-03	Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment [Including: Corrigendum 1 (2012)]	3-126
IEC	60601-1-2 Edition 4.1 2020-09 Consolidated Version	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	19-36

Standards Developing Organization	Designation Number and Edition Date	Standard Title	FDA Recognition Number
ISO	10993-1 Fifth edition 2018-08	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	2-258
ISO	10993-5 Third edition 2009-06-01	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	2-245
ISO	10993-10 Fourth edition 2021-11	Biological evaluation of medical devices - Part 10: Tests for skin sensitization	2-296
ISO	10993-23 First edition 2021-01	Biological evaluation of medical devices - Part 23: Tests for irritation	2-291
ISO	14971 Third Edition 2019-12	Medical devices - Application of risk management to medical devices	5-125
UL ANSI	2900-1 First Edition 2017	Standard for Safety Standard for Software Cybersecurity Network-Connectable Products Part 1: General Requirements	13-96
IEC	60086-4 Edition 5.0 2019-04	Primary batteries - Part 4: Safety of lithium batteries [Including: Corrigendum 1 (2019) and Corrigendum 2 (2020)]	19-40
ASTM	D4169-22	Standard Practice for Performance Testing of Shipping Containers and Systems	14-576

12.5.7 Conclusion

Based on the same intended use statement, technological characteristics, risk evaluations, device verification and validation testing, and clinical evaluation, the Otsuka Digital Feedback Device does not raise new safety or effectiveness questions and is equivalent to the predicate device.