September 16, 2024

Senseonics, Incorporated
Mukul Jain
Chief Operating Officer
20451 Seneca Meadows Parkway
Germantown, Maryland 20876-7005

Re: K241335
Trade/Device Name: Eversense 365 Continuous Glucose Monitoring (CGM) System
Regulation Number: 21 CFR 862.1357
Regulation Name: Integrated Continuous Glucose Monitoring System With Sensor Containing Dexamethasone Acetate
Regulatory Class: Class II
Product Code: SBA
Dated: May 10, 2024
Received: May 13, 2024

Dear Mukul Jain:

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 and Part 809); 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,

Joshua Balsam -S

Joshua M. Balsam, Ph.D.
Branch Chief
Division of Chemistry and
Toxicology Devices
OHT7: Office of In Vitro Diagnostics
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241335

Device Name
Eversense 365 Continuous Glucose Monitoring (CGM) System

Indications for Use *(Describe)*
The Eversense 365 Continuous Glucose Monitoring (CGM) System is indicated for continually measuring glucose levels for up to 1 year in people (18 years or older) with diabetes. The system is indicated for use to replace fingerstick blood glucose measurements for diabetes treatment decisions.

The system is intended to:
• Provide real-time glucose readings.
• Provide glucose trend information.
• Provide alerts for the detection and prediction of episodes of low blood glucose (hypoglycemia) and high blood glucose (hyperglycemia).

Historical data from the system can be interpreted to aid in providing therapy adjustments. These adjustments should be based on patterns and trends seen over time.

The Eversense 365 CGM System is also intended to autonomously communicate with digitally connected devices, including automated insulin dosing (AID) systems. The Eversense 365 CGM System can be used alone or in conjunction with these digitally connected medical devices for the purpose of managing diabetes.

The system is intended for single patient use and requires a prescription.

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.

510(k) SUMMARY

Applicant Information

Applicant/ 510(k) Owner: Senseonics, Incorporated
20451 Seneca Meadows Parkway
Germantown, Maryland 20876-7005
Registration Number: 3009862700

Contact: Mukul Jain, Ph.D.
Chief Operating Officer
Senseonics, Incorporated
20451 Seneca Meadows Parkway
Germantown, Maryland 20876-7005

Phone: (301) 556-1653
Fax: (301) 515-0988
E-mail: Mukul.Jain@senseonics.com

Date of Preparation: 13 September 2024

510(k) Number: K241335

Device and Classification Information

Trade Name:	Eversense 365 Continuous Glucose Monitoring (CGM) System
Common Name:	iCGM
Classification Regulation:	21 CFR 862.1357
Regulation Name:	Integrated continuous glucose monitoring system with sensor containing dexamethasone acetate
Product Code:	SBA
Class:	2
Panel:	Clinical Chemistry

Device Description

The Eversense 365 Continuous Glucose Monitoring (CGM) System provides continuous glucose measurements over a 40-400 mg/dL range. The system calculates glucose, trends and provides alerts for high and low glucose available for display on a mobile platform. It consists of a glucose Sensor (the Eversense 365 Sensor) that is inserted under the skin using Insertion Tools;

an externally worn Eversense 365 Smart Transmitter (Transmitter); and the Eversense 365 App, which runs on a compatible handheld device (HHD), such as a smartphone. The inserted Sensor is a radiofrequency (RF)-powered device that collects readings and sends them to the Transmitter. The Transmitter calculates, stores, and transmits the glucose data via Bluetooth Low Energy (BLE) to the Eversense 365 App on an HHD.

The CGM System consists of three principal components.

1. **Sensor:** The Sensor, inserted subcutaneously, receives RF-power from the Transmitter to measure interstitial fluid glucose every 5 minutes. The Sensor sends fluorescence readings or data to the Transmitter for calculation and storage of glucose values. The Sensor has a silicone collar component that contains an anti-inflammatory steroid drug (dexamethasone acetate) that elutes locally to reduce tissue inflammation around the Sensor. The Sensor operating life is up to one year or until the device's end-of-life is reached, whichever occurs first. The Sensor is provided sterile, for single use in a Sensor Holder. The Sensor is inserted using the provided Insertion Tools.

2. **Transmitter:** The Transmitter, worn externally over the inserted Sensor, is a device with rechargeable battery that powers the Sensor, calculates the glucose values from the Sensor-measured fluorescence readings, and using secure BLE wirelessly sends the glucose information to the Eversense 365 App for display on the HHD. An adhesive patch holds the Transmitter in place. The Transmitter is charged using the provided power cord and charge adapter. The Transmitter also provides vibration signals for alerts and notifications, such as low glucose levels, irrespective of whether the Eversense 365 App is in the vicinity or not.

3. **App:** The Eversense 365 App is a software application that runs on an HHD (e.g., compatible mobile device) for display of glucose information provided by the Transmitter. The Eversense 365 App receives and displays the calculated glucose information from the Transmitter, including glucose trend information and glucose alerts. The Eversense 365 App also allows the user to calibrate the CGM System. It also communicates with the Senseonics server for a one-time download of calibration parameters specific for each Sensor following the insertion as part of the linking process. The Eversense 365 App also provides the user an option to upload the data to Senseonics Data Management System (DMS) for historic viewing and storing of glucose data.

Indication for Use

The indication for use is shown below.

> The Eversense 365 Continuous Glucose Monitoring (CGM) System is indicated for continually measuring glucose levels for up to 1 year in people (18 years or older) with diabetes. The system is indicated for use to replace fingerstick blood glucose measurements for diabetes treatment decisions.

The system is intended to:

• Provide real-time glucose readings.

• Provide glucose trend information.

• Provide alerts for the detection and prediction of episodes of low blood glucose (hypoglycemia) and high blood glucose (hyperglycemia).

Historical data from the system can be interpreted to aid in providing therapy adjustments. These adjustments should be based on patterns and trends seen over time.

The Eversense 365 CGM System is also intended to autonomously communicate with digitally connected devices, including automated insulin dosing (AID) systems. The Eversense 365 CGM System can be used alone or in conjunction with these digitally connected medical devices for the purpose of managing diabetes.

The system is intended for single patient use and requires a prescription.

Predicate Device Identification for Substantial Equivalence Comparison

For purposes of demonstrating substantial equivalence, the following predicate devices was selected:

- Senseonics Eversense AP Continuous Glucose Monitoring (CGM) System by Senseonics, Incorporated authorized via DEN230052

The predicate device has been authorized by FDA for marketing in the US and has not been subject to a design-related recall.

Comparison of the Indication for Use and Intended Use between the Eversense 365 CMG System and the Predicate Eversense AP CGM System

The Eversense 365 CGM System has the same intended use as the predicate device Eversense AP CGM System (Table 1). There is one difference in the indication for use statements: the Eversense 365 CGM System is used for up to 1 year while the Eversense AP CGM System is used for up to 6 months. Importantly, both CGM systems are for long-term use to provide real-time glucose levels to guide diabetes treatment decisions and manage diabetes for patients (18 years or older), including communicating digitally with other medical devices, such as automated insulin dosing systems.

Table-1. Comparison of the Intended Use of the Eversense 365 CGM System to the Predicate Eversense AP CGM System (DEN230052)

Characteristic	Eversense 365 CGM System	Eversense AP CGM System (DEN230052)	Comparison
Manufacturer:	Senseonics	Senseonics	Same
Class:	2	2	Same

Characteristic	Eversense 365 CGM System	Eversense AP CGM System (DEN230052)	Comparison
Regulation: **Product Code:** **Common Name:**	21 CFR 862.1357 SBA iCGM	21 CFR 862.1357 SBA iCGM	
Indication for Use	…is indicated for continually measuring interstitial fluid glucose levels for up to 1 year in people (18 years and older) with diabetes. The system is indicated for use to replace fingerstick blood glucose measurements for diabetes treatment decisions. The system is intended to: • Provide real-time glucose readings. • Provide glucose trend information. • Provide alerts for the detection and prediction of episodes of low blood glucose (hypoglycemia) and high blood glucose (hyperglycemia). …is also indicated to communicate with digitally connected medical devices, including automated insulin dosing (AID) systems. The CGM can be used alone or in conjunction with these digitally connected medical devices for the purpose of managing diabetes.	…is indicated for continually measuring interstitial fluid glucose levels for up to 6 months in people (18 years and older) with diabetes. The system is indicated for use to replace fingerstick blood glucose measurements for diabetes treatment decisions. The system is intended to: • Provide real-time glucose readings. • Provide glucose trend information. • Provide alerts for the detection and prediction of episodes of low blood glucose (hypoglycemia) and high blood glucose (hyperglycemia). …is also indicated to communicate with digitally connected medical devices, including automated insulin dosing (AID) systems. The CGM can be used alone or in conjunction with these digitally connected medical devices for the purpose of managing diabetes.	Different: Different length of Sensor wear time. Difference in Sensor wear does not affect intended use as both CGM Systems share the same purpose, function, principles of operation, and clinical use in addition to other factors.
Purpose:	• To provide real-time glucose measurements for diabetes treatment decisions and to manage diabetes	• To provide real-time glucose measurements for diabetes treatment decisions and to manage diabetes	Same
Functions:	• Provides real-time glucose measurements • Provides glucose trend information	• Provides real-time glucose measurements • Provides glucose trend information	Same

Characteristic	Eversense 365 CGM System	Eversense AP CGM System (DEN230052)	Comparison
	• Provides alerts and predictive alerts for hypoglycemia and hyperglycemia • Provides remote monitoring capabilities • Communicates digitally with medical devices (automated insulin dosing systems)	• Provides alerts and predictive alerts for hypoglycemia and hyperglycemia • Provides remote monitoring capabilities • Communicates digitally with medical devices (automated insulin dosing systems)	
Principle of Operation:	• Glucose binds to the Sensor indicator molecule causing increase in fluorescence intensity. • Fluorescence is measured by the Sensor's internal optical system. • Transmitter calculates glucose values from the fluorescence measurements and communicates these values to other devices.	• Glucose binds to the Sensor indicator molecule causing increase in fluorescence intensity. • Fluorescence is measured by the Sensor's internal optical system. • Transmitter calculates glucose values from the fluorescence measurements and communicates these values to other devices.	Same
Clinical Use:	Manage diabetes	Manage diabetes	Same
Analyte:	Glucose	Glucose	Same
Specimen:	Interstitial fluid	Interstitial fluid	Same
Wear Location:	Upper arm	Upper arm	Same
Sensor Contact:	Tissue	Tissue	Same
Transmitter Contact:	Intact skin	Intact skin	Same
Sensor Life:	Up to 1 year (Automatically shuts down after grace period)	Up to 6 months (Automatically shuts down, no grace period)	Different
Users:	People with diabetes (18 years or older)	People with diabetes (18 years or older)	Same
Prescription:	Yes	Yes	Same
Use Environment:	Home	Home	Same

Comparison of the Technological Characteristics between the Eversense 365 CGM System and the Predicate Eversense AP CGM System

There are many similarities in technological characteristics between the Eversense 365 CGM System and the predicate Eversense AP System, but there are some differences.

Each CGM system consists of the same components: an implantable sensor, insertion tools, transmitter, adhesive patch for the transmitter, and a mobile medical application (MMA) (see Table 2). Two components have been updated to achieve the longer Sensor life and reduced calibration frequency: the sensor and the transmitter. The software application has also been updated to accommodate the longer Sensor life and reduced calibration frequency.

Table-2. Comparison of the System Components of the Eversense 365 CGM System and the Predicate Eversense AP CGM System

Technological Characteristic	**Eversense 365 CGM System**	**Eversense AP CGM System (DEN230052)**	**Comparison**
System Components	Sensor Insertion Tools Transmitter Adhesive Patches Mobile App (MMA)	Sensor Insertion Tools Transmitter Adhesive Patches Mobile App (MMA)	Same
Sensor	Eversense 365 Sensor	Eversense AP Sensor	Different
Insertion Tools	Eversense Insertion Tools	Eversense Insertion Tools	Same
Transmitter	Eversense 365 Transmitter	Eversense AP Transmitter	Different
Adhesive Patch	Eversense 365 Adhesive Patches	Eversense Adhesive Patches	Same
Mobile Medical App (MMA)	Eversense 365 App	Eversense AP App	Different
Principles of Operation	• Glucose binds to the Sensor indicator molecule causing increase in fluorescence intensity. • Fluorescence is measured by the Sensor's internal optical system. • Transmitter calculates glucose values from the fluorescence measurements and communicates these values to other devices.	• Glucose binds to the Sensor indicator molecule causing increase in fluorescence intensity. • Fluorescence is measured by the Sensor's internal optical system. • Transmitter calculates glucose values from the fluorescence measurements and communicates these values to other devices.	Same

Performance Data

This 510(k) notification provided performance data to establish the substantial equivalence of the Eversense 365 CGM System and to demonstrate the Eversense 365 CGM System meets the Special Controls.

Sterility and Shelf-Life: The Eversense 365 Sensor with its holder and the Insertion Tools are provided sterile for single-use, and are sterilized using ethylene oxide (EO). The sterilization process was validated in accordance with ISO 11135-1 and in consideration of ISO 11135-2 to a sterility assurance level (SAL) of 10^{-6}. The shelf-life has been established at 13 months with recommended storage between 2°C and 8°C (36°F and 46°F).

Biocompatibility: Biocompatibility studies were selected and performed in consultation with international recognized safety standards (ISO 10993-1, Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing) and in accordance with the FDA guidance document. All studies were conducted in compliance with 21 CFR Part 58 - Good Laboratory Practice for Nonclinical Laboratory Studies (GLPs). All studies had passing results (see table).

Table-3. Summary of the Biocompatibility Tests and Results for the Eversense 365 Sensor

Biocompatibility Test	ISO Standard	Results
Cytotoxicity	ISO 10993-5	Pass – Not cytotoxic
Sensitization	ISO 10993-10	Pass - -Not Sensitizing
Irritation	ISO 10993-10	Pass – Nonirritant
Systemic Toxicity (Material Mediated Pyrogen)	ISO 10993-11	Pass – Not pyrogenic
Subchronic Toxicity and Implantation (4 and 13 week implant study)	ISO 10993-6	Pass - Not systemically toxic
Chronic Toxicity and Implantation (26 week implant study)	ISO 10993-6	Pass - Not systemically toxic
Genotoxicity/Carcinogenicity (Bacterial Reverse Mutation)	ISO 10993-3	Pass - Non-mutagenic
Genotoxicity/Carcinogenicity (Mouse Lymphoma)	ISO 10993-3	Pass - Non-mutagenic
Chemical Characterization	ISO 10993-17 ISO 10993-18	Pass - no leachables/extractables from the Sensor are likely to cause adverse effects in patients
Particulate Tests	ISO 14708-1	Pass - Particulate count did not exceed requirement

Software: Software verification and validation testing has been performed in accordance with IEC 62304 and the FDA guidance document for software. Verification and validation testing included unit test, system level verification tests (which included functional testing to demonstrate the device meet its requirements), traceability linking and validation testing to ensure the software conforms to user needs and intended uses.

Cybersecurity: Cybersecurity information in accordance with the FDA guidance document for cybersecurity has been provided to demonstrate cybersecurity risks have been mitigated and that the risk of cybersecurity threats is deemed acceptable.

Electromagnetic Compatibility (EMC): Electromagnetic Compatibility and Wireless Coexistence performance characteristics were established through nonclinical testing of the predicate device and are applicable to the Eversense 365 Transmitter. The Transmitter has undergone testing to demonstrate that the device meets the standards for EMC compatibility: IEC 60601-1-2, 4.1 Edition, Medical electrical equipment – Part 1-2, General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests.

Electrical, Mechanical and Thermal: Electrical Safety performance characteristics were established through nonclinical testing of the predicate device and are applicable to the Eversense 365 CGM System. The Transmitter has undergone testing to demonstrate that the device meets the international standards: IEC 60601-1, 3rd Edition, Medical electrical equipment – General requirements for basic safety and essential performance.

The environmental and mechanical requirements of the Eversense 365 Sensor and Eversense 365 Transmitter were tested to verify requirements were met.

Performance – Bench:
Appropriate testing was performed to confirm the devices meet specified performance requirements:

- Chemical interference testing following standard EP7-02, Interference Testing in Clinical Chemistry was performed to verify that prior tests performed on the predicate device are applicable to the subject device, and that no new interference substances are identified.
- MRI exposure testing following standard ISO/TS 10974, Assessment of the Safety of Magnetic Resonance Imaging for Patients with an Active Implantable Medical Device was performed to verify the Sensor is MRI Conditional.
- Ultrasound exposure testing following standard ISO 14708-1, Implants for surgery -- Active implantable medical devices -- Part 1: General requirements for safety, marking and for information to be provided by the manufacturer was performed to verify Sensors maintain functionality after exposure to ultrasound.
- Adhesion testing was performed to verify adhesive patches meet their functional requirements.
- Testing was performed to verify the Insertion Tool is capable of retaining the Sensor.

Performance – Clinical:

The ENHANCE Study, conducted under IDE application G210196, evaluated the accuracy and safety of the Eversense 365 CGM System through 365 days post-insertion.

The ENHANCE Study is a prospective, multi-center study, whereby 110 adult subjects (ages 18 years and older) were inserted with the Eversense 365 CGM System at 4 sites in the United States. One hundred and ten (110) participants with diabetes had at least one sensor inserted into their upper arms by trained Investigators.

The accuracy of the Eversense 365 CGM System was evaluated during clinic visits comparing CGM glucose values and plasma glucose values measured using a bedside glucose analyzer. For qualified subjects, hyperglycemia and hypoglycemia challenges were performed during clinic visits to measure accuracy over a range of glucose values. The study utilized an FDA-accepted laboratory-based glucose measurement method (2300 Stat Plus Glucose & Lactate Analyzer, Yellow Springs Instruments, Yellow Springs, OH, USA) to evaluate the accuracy of the Eversense 365 CGM System.

Accuracy visits were conducted from insertion and through Day 365 to assess performance in the early post Sensor insertion period and through 12 months. In the interest of testing Sensor performance across the entire reporting range of the device (40-400 mg/dL), data were collected in the hypoglycemic and hyperglycemic ranges by having eligible participants participate in either hypoglycemia and hyperglycemia challenges at each visit, where participant's glucose levels were artificially raised or lowered to certain levels for prescribed periods of time.

The ENHANCE Study relied upon many of the same design features and elements of the clinical studies that supported past Eversense CGM System approvals, including the original PMA P160048, the non-adjunctive use P160048/S006, two Panel-Track PMA Supplements (P160048 S016 and S021). The ENHANCE study also supported the *De Novo* request (DEN230052) that was recently granted.

The ENHANCE Study was conducted in compliance with 21 CFR Parts 50, 56, and 812.

The results from the ENHANCE Study demonstrated that accuracy of the Eversense 365 CGM System and that it met all Special Controls for accuracy (see Tables 4-6). The safety profile was also comparable to Eversense CGM Systems. The majority of Eversense 365 Sensors (90%) functioned through 12 months.

Table-4. Percent and Point Accuracy Between iCGM and YSI by iCGM Glucose Ranges: iCGM Special Controls (1)(v)(A)-(F)

iCGM Special Control	**iCGM Glucose Range (mg/dL)**	**Matched Pairs (N)**	**Eversense 365 CGM System Performance**		**Special Control 95% LB**
			Point Estimate	**95% LB**	
System Agreement to Reference within ± 15 mg/dL/15%					
(1)(v)(A)	< 70	3040	87.2%	86.3%	>85%
(1)(v)(B)	70-180	23049	81.9%	81.5%	>70%
(1)(v)(C)	>180	14408	89.3%	88.9%	>80%
System Agreement to Reference within ± 40 mg/dL/40%					
(1)(v)(D)	< 70	3040	99.0%	98.7%	>98%
(1)(v)(E)	70-180	23049	99.4%	99.3%	>99%
(1)(v)(F)	>180	14408	99.8%	99.7%	>99%

Table-5. iCGM System Agreement to Reference within Overall iCGM Glucose Range: iCGM Special Control (1)(v)(G)

iCGM Glucose Range (mg/dL)	Matched Pairs (N)	Pointe Estimate of Percent Within 20%	95% LB	Special Control 95% LB
Overall (40-400) mg/dL	40497	92.0%	91.8%	>87%

Table-6. iCGM Special Controls (1)(v)(H)-(K) Through 365 Days

iCGM Special Control	iCGM Glucose Range mg/dL	Matched Pairs (N)	Performance Metric	Eversense 365 Results
(1)(v)(H)	< 70	40497	No blood glucose value > 180 mg/dL	0 values > 180 mg/dL
(1)(v)(I)	>180	40497	No blood glucose value < 70 mg/dL	0 values < 70 mg/dL
(1)(v)(J)	40-400	210	No more than 1% of iCGM values indicate a positive rate of change > 1mg/dL/min when the corresponding true negative rate of change is < -2mg/dL/min	0.5% (1/210)
(1)(v)(K)	40-400	806	No more than 1% of iCGM values indicate a negative rate of change < -1mg/dL/min when the corresponding true positive rate of change is >2mg/dL/min	0.4% (3/806)

Human Factors:
No new Human Factors testing was performed to support this 510(k) notification. A comparative Use Related Risk Analysis was performed to support this 510(k) notification.

Special Controls:
Evaluation and adherence to the Special Controls for the Eversense 365 CGM System demonstrates assurance of the safety and effectiveness and substantial equivalence to the predicate device (DEN230052).

Conclusion

The comparisons and performance data demonstrate that the Eversense 365 CGM System meets the Special Controls for an integrated continuous glucose monitoring system with sensor containing dexamethasone acetate, and is substantially equivalent.