510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT

I Background Information:

A 510(k) Number

K241335

B Applicant

Senseonics, Incorporated

C Proprietary and Established Names

Eversense 365 Continuous Glucose Monitoring (CGM) System

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
SBA	Class II	21 CFR 862.1357 - Integrated Continuous Glucose Monitoring System With Sensor	Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

New device.

B Measurand:

Glucose in interstitial fluid.

C Type of Test:

Quantitative, fluorescent based.

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

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.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

The smart transmitter is incompatible with magnetic resonance imaging (MRI) procedures. The smart transmitter is MR Unsafe and MUST BE REMOVED before undergoing an MRI (magnetic resonance imaging) procedure.

The system is contraindicated in people for whom dexamethasone or dexamethasone acetate may be contraindicated.

Mannitol or sorbitol, when administered intravenously, or as a component of an irrigation solution or peritoneal dialysis solution, may increase blood mannitol or sorbitol concentrations and cause falsely elevated readings of sensor glucose results. Sorbitol is used in some artificial sweeteners, and concentration levels from typical dietary intake do not impact sensor glucose results.

Antibiotics of the tetracycline class (including tetracycline, doxycycline, minocycline and tigecycline) may falsely lower sensor glucose readings. Users should not rely on sensor glucose readings while taking tetracyclines.

The system has not been tested in the following populations: women who are pregnant or nursing, people under the age of 18, critically ill or hospitalized patients, people receiving immunosuppressant therapy, chemotherapy or anti-coagulant therapy, those with another active implantable device, e.g., an implantable defibrillator (passive implants are allowed, e.g., cardiac stents), those with known allergies to or using systemic glucocorticoids (excluding topical, optical or nasal, but including inhaled). The system's accuracy hasn't been tested in these populations, and sensor glucose readings may be inaccurate, resulting in missing a severe low or high glucose event.

The Apple Watch is a secondary display of data and should not be used in place of the primary CGM display.

D Special Instrument Requirements:

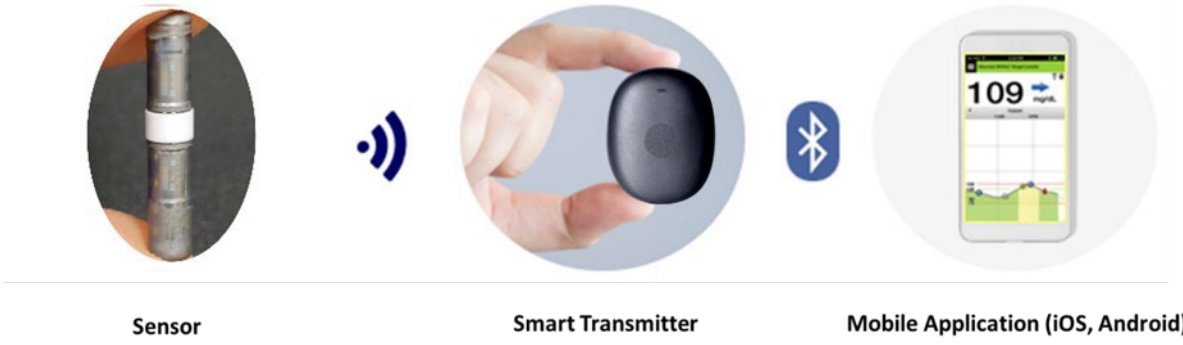
Not applicable.

IV Device/System Characteristics:

A Device Description:

The Eversense 365 Continuous Glucose Monitoring (CGM) System provides glucose measurements every 5 minutes 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 by a healthcare provider under the skin using Insertion Tools (Eversense Insertion Tools); an externally worn Transmitter (Eversense 365 Smart Transmitter); and the Eversense Mobile Medical Application (MMA, Eversense 365 Mobile App), which runs on a handheld device, such as a Smartphone running on Android or iOS operating systems (see Figure 1). 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 an MMA on a handheld device (HHD).

Figure 1. Eversense 365 Continuous Glucose Monitoring System



B Principle of Operation:

The Eversense 365 CGM System detects glucose levels in the interstitial fluid just beneath the skin. The Eversense 365 Sensor uses a selective, fully reversible binding between glucose and a proprietary fluorescent indicator macromolecule that is grafted on the surface of the Sensor. Glucose binding by the indicator macromolecule results in an increase in fluorescence intensity. Glucose signal transduction is accomplished by measuring the fluorescence intensity modulation using the Sensor's optical system. The transmitter converts the signal using an algorithm to a glucose value read in mg/dL, which is then transmitted to the MMA for the user to see and use accordingly.

C Instrument Description Information:

1. Instrument Name:

   Eversense 365 Continuous Glucose Monitoring (CGM) System

2. Specimen Identification:

   Not applicable.

3. Specimen Sampling and Handling:

   Not applicable.

4. Calibration:

   There are three periodic calibration phases during the wear life of the sensor:

   A. Initialization Phase (after 24-hour Warm-Up Phase)

   During this phase, 4 fingerstick blood glucose calibrations are required.

   - The 4 calibrations must be spaced 2 to 12 hours apart. All 4 calibrations must be completed within a 36 hour period. After 8 hours without a calibration entry, no glucose data will be displayed.

   B. 1 Daily Calibration Phase Through Day 13

   After the initialization phase, the 1 Daily Calibration Phase requires a blood glucose fingerstick calibration every 24 hours for 13 days.

   - 24 hours after your last successful calibration, the system prompts you to calibrate.

   C. 1 Weekly Calibration Phase Starting Day 14

   The 1 Weekly Calibration Phase requires a blood glucose fingerstick calibration once a week.

   - 1 week after your last successful calibration, the system prompts the user to calibrate.

5. Quality Control:

   Not applicable.

V Substantial Equivalence Information:

A Predicate Device Name(s):
Eversense AP CGM System

B Predicate 510(k) Number(s):
DEN230052

C Comparison with Predicate(s):

Device & Predicate Device(s):	K241335	DEN230052
Device Trade Name	Eversense 365 CGM System	Eversense AP CGM System
General Device Characteristic Similarities		
Intended Use/Indications For Use	An integrated continuous glucose monitoring system (iCGM) is intended to automatically measure glucose in bodily fluids continuously or frequently for a specified period of time. iCGM systems are designed to reliably and securely transmit glucose measurement data to digitally connected devices, including automated insulin dosing systems, and are intended to be used alone or in conjunction with these digitally connected medical devices for the purpose of managing a disease or condition related to glycemic control.	Same
Measurement Range	40-400 mg/dL	Same
Glucose Sensing Element of Indicator Hydrogel	Indicator monomer (TFM) – fully reversible binding of glucose	Same

Method of Measuring Glucose	Fluorescence	Same
Sensor Dimensions	Approximately 3.5mm x 18.3mm	Same
DXA Collar	A silicone collar attached to the encasement (using a silicone adhesive) which elutes locally an anti-inflammatory steroid (1.75 mg of DXA) to minimize local foreign body reaction	Same
Storage Conditions	2-8ºC	Same
Shelf-Life	13 months (from the date of application of the glucose-indicating hydrogel)	Same
Operational Condition	Temperature: 5-40°C Humidity: 15-90% RH Atmospheric Pressure: 700-1,060 hPa	Same
General Device Characteristic Differences		
Sensor Life	Up to 1 year (Automatically shuts down after grace period)	Up to 6 months (Automatically shuts down, no grace period)
Cal Frequency	Varies during wear: 4 cals in 36 hours 1 cal/day through Day 13 1 cal/week starting Day 14	Varies during wear: 4 cals in 36 hours 2 cals/day through Day 21 1 cal/day starting Day 22

VI Standards/Guidance Documents Referenced:

60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION, Medical electrical equipment – General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic compatibility – Requirements and Tests

60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION, Medical electrical equipment – 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

IEC 62133-2 2017/AMD1:2021, Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and batteries made from them, for use in portable applications – Part 2: Lithium systems.

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

ISO 14708-1, 2014, Active Implantable Medical Devices - Part 1: General Requirements for Safety, Marking, and for Information to be provided by the Manufacturer

IEC 62366-1 :2015+AMD1 :2020 (Consolidated Text), Medical devices Part 1: Application of usability engineering to medical devices including Amendment 1

UL 1642, 5th Edition. Standard for Safety – Lithium Batteries

IEEE ANSI USEMCSC C63.27-2021, American National Standard for Evaluation of Wireless Coexistence

ISO TS 10974 Second edition 2018, Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device

ASTM F2052-21, Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment

ASTM F2213-17, Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment

ISO 10993-1:2018, Biological evaluation of medical devices – Part 1: Evaluation and testing

ISO 10993-3 Third edition 2014-10-1, Biological evaluation of medical devices Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity

ANSI AMMI ISO 10993-5:2009/(R)2014, Biological evaluation of medical devices – Part 5: Tests for cytotoxicity: in vitro methods

ISO 1110993-6 Third edition 2016-12-01, Biological evaluation of medical devices – Part 6: Tests for local effects after implantation

ISO 10993-10 Fourth edition 2021-11, Biological evaluation of medical devices – Part 10: Tests for skin sensitization

ISO 10993-11:2017, Biological evaluation of medical devices Part 11: Tests for systemic toxicity.

ISO 10993-12:2021, Biological evaluation of medical devices – Part 12: Sample preparation and reference materials

ISO 10993-17:2002/(R)2012, Biological evaluation of medical devices – Part 17: Establishment of allowable limits for leachable substances

ISO 10993-18:2020-01, Biological evaluation of medical devices – Part 18: Chemical characterization of materials

ISO 1110993-23 First edition 2021-01, Biological evaluation of medical devices – Part 23: Tests for Irritation

ISO 10993-7 Second edition 2008-10-15, Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals

EN ISO 11135:2014/Al:2018, Sterilization of Health Care Products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

EN ISO 111737-1 Third edition 2018-01 [Including AMDl:2021], Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products

ISO 11737-2: 2019, Sterilization of medical devices – Microbiological methods – Part 2: test of sterility performance in the definition, validation and maintenance of a sterilization process

ISO 11607-1:2019, Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems

ISO 11607-2:2019, Packaging for terminally sterilized Medical Devices – Part 2: Validation Requirements for forming, sealing and assembly processes

ASTM F1980-16, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

ASTM F1886/F1886M-16, Standard Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection

ASTM F2096-11 (Reapproved 2019), Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)

ASTM D3078-02 (Reapproved 2021)e 1, Standard Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission

ASTM F88/F88M-23, Standard Test Method for Seal Strength of Flexible Barrier Materials

AAMI TIR57:2016, Principles for medical device security - Risk management

AAMI TIR97:2019, Principles for medical device security - Postmarket risk management for device manufacturers

CLSI. EP07 3rd Edition Interference Testing in Clinical Chemistry

ISO 14155 Third edition 2020-07, Clinical investigation of medical devices for human subjects - Good Clinical Practice

ISO 14971:2019, Medical devices – Application of Risk Management to Medical Devices

ISO 15223-1:2021, Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 1: General requirements

ISO 14708-1:2014 Implants for surgery -- Active implantable medical devices -- Part 1: General requirements for safety, marking an Implants for surgery -- Active implantable medical devices -

Part 1: General requirements for safety, marking and for information to be provided by the manufacturer

IEC 62304:2006/ A 1 :2016, Medical Device Software – Software life cycle processes

Content of Premarket Submissions for Device Software Functions – Guidance for Industry and Food and Drug Administration Staff, document issued on June 14, 2023

Off-The-Shelf Software Use in Medical Devices - Guidance for Industry and Food and Drug Administration Staff, document issued on September 27, 2019

Radio Frequency Wireless Technology in Medical Devices - Guidance for Industry and Food and Drug Administration Staff, document issued on August 14, 2013

Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" – Guidance for Industry and Food and Drug Administration Staff, document issued on September 4, 2020

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

iCGM performance was evaluated in clinical studies described in Section C(3) below. A subset of subjects (n=36) subjects wore two Eversense 365 Sensors concurrently to evaluate precision. The between-Sensor precision was characterized based on the paired CGM system readings from Sensors in each arm worn simultaneously; one on the left arm and one on the right arm. The precision data are shown in the table below. Precision is described as Standard Deviation (SD), Paired Absolute Difference (PAD), Paired Absolute Relative Difference (PARD) and Coefficient of Variation (CV%).

Range of Mean CGM Glucose (mg/dL)	Number (CGM, CGM) pairs	Number of subjects	SD (mg/dL)	PAD (mg/dL)	PARD (%)	CV (%)
Overall	82,731	32	17.5	12.3	8.0	5.7
<70	3,911	28	10.1	7.4	12.6	8.9
70-180	50,997	32	14.0	10.2	8.2	5.8
>180	27,823	32	23.2	16.8	7.0	4.9

2. Linearity:

The reportable range for the Eversense 365 CGM System is 40 to 400 mg/dL. Data supporting this claimed measurement range were generated in the clinical study described in Section C(3) below.

3. Analytical Specificity/Interference:

Mannitol or sorbitol, when administered intravenously, or as a component of an irrigation solution or peritoneal dialysis solution, may increase blood mannitol or sorbitol concentrations and cause falsely elevated readings of the sensor glucose results. Sorbitol is used in some artificial sweeteners, and concentration levels from typical dietary intake do not impact sensor glucose results.

With the Eversense 365 CGM System, medications of the tetracycline class, such as tetracycline, doxycycline, minocycline, tigecycline, may falsely lower glucose. A negative bias may create a situation in which a user inappropriately increases their carbohydrate intake or does not dose with insulin during a time in which their blood glucose concentration is euglycemic or hypoglycemic, hazardous situations which do not present imminent risk to the user but which do increase risks associated with hyperglycemia. Risks resulting from tetracycline interference are mitigated through the information provided to users and healthcare providers (HCPs) in the "*Warning*", "*Medication*", "*Making Treatment Decisions with Eversense 365*" and the "*Troubleshooting: Making Treatment Decisions*" sections of the patient User Guide and the "*Warnings*" section of the HCP instructions for use.

4. Assay Reportable Range:

See linearity section above.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

The Eversense 365 Sensor has a storage shelf-life of 13 months that was evaluated at 2-8º C (35-46º F).

The Eversense 365 Transmitter requires daily charging. The internal battery of the transmitter is sufficiently durable to function for 12 months as intended following its maximum storage time of 12 months. Shelf life was evaluated by functional test after 40 days of accelerated aging at 131°F (equivalent to 1 year real-time).

6. Detection Limit:

If a glucose measurement is less than 40 mg/dL, the result is displayed by the system as 'LO'. If a glucose measurement exceeds 400 mg/dL, the result is displayed as 'HI'. Data supporting this claimed measurement range was generated in the clinical study described in Section C(3) below.

7. Assay Cut-Off:

   Not applicable.

8. Accuracy (Instrument):

   Not applicable.

9. Carry-Over:

   Not applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:

   Not applicable. Accuracy is determined by comparing iCGM values to an FDA cleared laboratory grade glucose analyzer (Yellow Springs Instrument 2300 STAT Plus™ Glucose Analyzer) and referred to as the "comparator method" in Section C(3) below.

2. Matrix Comparison:

   Not applicable. Interstitial fluid is the only indicated matrix.

C Clinical Studies:

1. Clinical Sensitivity:

   Not applicable.

2. Clinical Specificity:

   Not applicable.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

   The ENHANCE study is a prospective, multi-center study, whereby 110 subjects (≥ 18 years of age) were inserted with the Eversense 365 CGM System at 4 sites in the United States. The investigation included both clinic visits and home use of the Eversense 365 CGM System. Thirty-six (36) subjects had two Eversense 365 Sensors inserted, and 74 subjects were inserted with one Eversense 365 Sensor in one arm.

Demographics

A summary of demographic characteristics for all Eversense 365 CGM System subjects is presented in the table below. Subjects had a mean age of 47 years and a mean body mass index (BMI) of 32 kg/m^2. Both males and females were represented in the study population.

Demographic	Value
Gender n (%)	
Male	69 (62.7)
Female	41 (37.3)
Age (years) [mean (SD)]	47.2 (13.7)
Min, Max	18, 77
Ethnicity n (%)	
Non-Hispanic	86 (78.2)
Hispanic	24 (21.8)
Race n(%)	
Caucasian	102 (92.7)
Black or African American	4 (3.6)
Asian	1 (0.9)
American Indian or Alaska Native	1 (0.9)
Native Hawaiian or Other Pacific Islander	0 (0.0)
More than One Race	2 (1.8)
Body Mass Index Class [mean (SD)] kg/m^2	32.0 (6.8)
Min, Max	19, 52
Normal (<25 kg/m^2) n (%)	12 (10.9)
Overweight (>25 and <30) n (%)	30 (27.3)
Obese (>30) n (%)	68 (61.8)

All accuracy data were collected during the in-clinic visits. The accuracy of the CGM glucose reading was assessed using metrics based on 40,718 matched pairs for the primary Sensor through clinic visits on Days 1, 7, 14, 22, 30, 60, 90, 120, 150, 180, 210, 240, 270, 300, 330, and 365 per protocol.

Accuracy was evaluated using paired CGM readings to comparator method values for the Eversense 365 CGM System. For values less than 70 mg/dL, the absolute difference in mg/dL between the two glucose results was calculated. For values greater than or equal to 70 mg/dL, the absolute difference (%) relative to Comparator Method values was calculated. The percentages of readings within 15/15% of Comparator Method values or 40/40% of Comparator Method values by CGM glucose ranges are shown in the table below.

Percent and Point Accuracy by iCGM Glucose Range (N=110)

iCGM Glucose Range	Matched Pairs (N)	Percent Within 15 mg/dL (95% LB)	Percent Within 40 mg/dL (95% LB)	Percent Within 15% (95% LB)	Percent Within 40% (95% LB)	Mean Bias (mg/dL) (95% UB)
<70 mg/dL	3,040	87.2 (86.3)	99.0 (98.7)	---	---	-5.4 (-5.0)
70-180 mg/dL	23,049	---	---	81.9 (81.5)	99.4 (99.3)	-1.9 (-1.7)
>180 mg/dL	14,408	---	---	89.3 (88.9)	99.8 (99.7)	0.7 (1.1)

Percentages of readings within 15/15% or 40/40% of comparator method values by Comparator glucose ranges.

Percent and Point Accuracy by Comparator Glucose Range (N=110)

Comparator Glucose Range	Matched Pairs (N)	Percent Within 15 mg/dL (95% LB)	Percent Within 40 mg/dL (95% LB)	Percent Within 15% (95% LB)	Percent Within 40% (95% LB)	Mean Bias (mg/dL) (95% UB)
<70 mg/dL	2,804	89.8 (88.9)	99.6 (99.4)	---	---	1.5 (1.9)
70-180 mg/dL	23,130	---	---	82.4 (82)	99.4 (99.3)	-0.3 (-0.1)
>180 mg/dL	14,563	---	---	88.2 (87.8)	99.9 (99.9)	-3.3 (-2.9)

*95% LB is the lower bound of the confidence interval and 95% UB is the upper bound of the confidence interval

Percentage of readings within 20% of comparator method values, including the 95% lower bound confidence interval, for the overall 40-400 mg/dL iCGM range is shown in the Table below.

iCGM agreement to Comparator through 365 Days

iCGM Glucose Range	Matched Pairs (N)	Percent Within 20% (95% LB)
Overall (40-400 mg/dL)	40,497	92.0 (91.8)

Percent of values within 15/15% mg/dL, 20/20% mg/dL, and 40/40% mg/dL stratified by glucose ranges of <54, 54-69, 70-180, 181-250, and >250 mg/dL for CGM and comparator method were also provided.

Eversense 365 CGM System Accuracy to Comparator within iCGM Glucose Ranges (N=110)

iCGM Glucose Range (mg/dL)	Number of paired iCGM-Comp	Percent Within 15 mg/dL	Percent Within 20 mg/dL	Percent Within 40 mg/dL	Percent Within 15%	Percent Within 20%	Percent Within 40%	Mean Bias (mg/dL)	MARD (%)
<54	687	76.3	88.2	98.3	--	--	--	-11.0	17.9
54-69	2,353	90.4	94.8	99.2	--	--	--	-3.8	11.1
70-180	23,049	--	--	--	81.9	90.9	99.4	-1.9	9.0
181-250	8,198	--	--	--	88.0	94.9	99.7	-2.4	7.7
>250	6,210	--	--	--	91.1	97.1	99.8	5.3	7.2

Eversense 365 CGM System Accuracy to Comparator within Comparator Glucose Ranges (N=110)

Comparator Glucose Range (mg/dL)	Number of paired iCGM-Comp	Percent Within 15 mg/dL	Percent Within 20 mg/dL	Percent Within 40 mg/dL	Percent Within 15%	Percent Within 20%	Percent Within 40%	Mean Bias (mg/dL)	MARD (%)
<54	358	90.2	95.0	99.4	--	--	--	3.9	15.8
54-69	2,446	89.8	96.7	99.6	--	--	--	0.8	12.5
70-180	23,130	--	--	--	82.4	91.4	99.4	-0.3	9.0
181-250	7,997	--	--	--	87.1	94.5	99.9	-3.1	7.8
>250	6,566	--	--	--	89.5	95.9	100.0	-2.9	7.5

Concurrence of iCGM values compared to the comparator method across the entire measuring range was also evaluated. iCGM glucose ranges of <40, 40-60, 61-80, 81-120, 121-160, 161-200, 201-250, 251-300, 301-350, 351-400, and >400 mg/dL were evaluated against comparator glucose ranges and percent of iCGM values within those ranges were reported.

Concurrence of Eversense 365 CGM System Reading and Comparator Values by iCGM Glucose Range (N=110)

iCGM (mg/dL)	Comparator Glucose Values (mg/dL)											
	<40	**40-60**	**61-80**	**81-120**	**121-160**	**161-200**	**201-250**	**251-300**	**301-350**	**351-400**	**>400**	**Total**
<40	14.5 %	71.1 %	9.2%	5.3%								76
40-60	0.2%	52%	44.6 %	3%	0.1%							1,411
61-80		13%	61.8 %	24.7 %	0.6%							3,449
81-120		0.3%	6.8%	76.1 %	16.4 %	0.5%	0%					9,149
121-160		0%	0.1%	14.2 %	71.2 %	13.7 %	0.8%	0%				8,638
161-200				0.1%	17%	65%	17.2 %	0.7%	0%			6,292
201-250					0.4%	15.8 %	66%	16.8 %	1%			5,348
251-300					0.1%	0.4%	17.5 %	63.8 %	17.4 %	0.7%		3,494
301-350							0.5%	28.1 %	64.5 %	6.6%	0.2%	2,052
351-400								3.3%	61.3 %	34%	1.4%	664
>400								0.6%	22.4 %	55.1 %	21.8 %	156

Concurrence of Eversense 365 CGM System Reading and Comparator Values by Comparator Glucose Range (N=110)

Comparator Glucose Range (mg/dL)	iCGM Glucose Values (mg/dL)											
	<40	**40-60**	**61-80**	**81-120**	**121-160**	**161-200**	**201-250**	**251-300**	**301-350**	**351-400**	**>400**	**Total**
<40	78.6%	21.4%										14
40-60	4.3%	58.2%	35.4%	2%	0.1%							1,261
61-80	0.2%	18.6%	62.8%	18.2%	0.2%							3,392
81-120	0%	0.5%	9.4%	76.5%	13.5%	0.1%						9,098
121-160		0%	0.2%	17.1%	70.2%	12.2%	0.2%	0%				8,755
161-200				0.7%	19.1%	66.2%	13.7%	0.2%				6,179
201-250				0%	1.4%	20.4%	66.5%	11.5%	0.2%			5,308
251-300					0%	1.1%	23.8%	59.1%	15.3%	0.6%	0%	3,774
301-350						0%	2.1%	25.1%	54.5%	16.8%	1.4%	2,427
351-400								5.3%	28.8%	47.8%	18.2%	473
>400									10.4%	18.8%	70.8%	48

Trend Accuracy

Trend accuracy describes the accuracy of the sensor during times of rapidly changing glucose and is characterized by slopes, such as from >2 mg/dL to <-2 mg/dL. Trend accuracy was assessed by the concurrence rate of the glucose rate of change (changes in mg/dL of glucose per minute) determined by the comparator values and the corresponding iCGM values for each CGM-comparator measured pairs (typically once every 15 minutes).

Comparator Rate Range (mg/dL/Min)	iCGM Rate Range (mg/dL/min)					iCGM-Comparator Pairs (n)
	< -2	[-2, -1)	[-1, 1]	(1, 2]	> 2	
< -2	41.4%	37.1%	21.0%	0.5%		210
[-2,-1)	13.4%	40.2%	44.2%	1.8%	0.4%	2,026
[-1,1]	1.1%	6.5%	85.3%	5.8%	1.3%	32,531
(1,2]	0.2%	0.7%	43.9%	36.9%	18.2%	2,861
> 2		0.4%	21.7%	28.6%	49.3%	803

Agreement when iCGM reads “LO” or “HI”

The Eversense 365 CGM System reports glucose readings between 40 and 400 mg/dL. When the system determines that the glucose reading is below 40 mg/dL, it displays “LO” in the MMA. When the system determines that the glucose level is >400 mg/dL, it displays “HI” in the MMA. Because the system does not display glucose values below 40 mg/dL or above 400 mg/dL, the comparisons to the actual blood glucose levels (using the laboratory comparator method) when the iCGM value is classified as “LO” or “HI” was evaluated separately. The cumulative percentages when the laboratory comparator values were less than certain glucose levels (for “LO”), and greater than certain glucose values (for “HI”) are presented in the table below.

iCGM Readings	iCGM Comparator Readings	<55	<60	<70	<80	>=80	Total
“LO”	N Cumulative Percent	54 71.1%	64 84.2%	71 93.4%	72 94.7%	4 5.3%	76

iCGM Readings	iCGM Comparator Readings	>340	>320	>280	>250	<=250	Total
“HI”	N Cumulative Percent	134 85.9%	143 91.7%	156 100.0%	156 100.0%	0 0%	156

Alert Performance

The tables in this section show the accuracy of the Eversense 365 CGM System's Low and High Glucose Alarms. The Alarm Rate tells the user how often the alarm is right or wrong. The Detection Rate tells the user how often the Eversense 365 CGM System is able to recognize and notify the user about a low or high glucose event (within 15 minutes before or after the event).

Low Glucose Alarm Performance

The low glucose alert rate shows how often the alert is right or wrong. The true alert rate is the % of time the iCGM alarmed when the blood glucose level was at or below the alert setting within 15 minutes before or after the iCGM alarmed (as confirmed by the comparator method). The false alert rate is the % of time the iCGM alarmed when the blood glucose level was above the alert setting within 15 minutes before or after the iCGM alarmed. The confirmed detection rate is the % of time the iCGM alarmed when the blood glucose level was at or below the alert setting within 15 minutes before or after the hypoglycemic event. The missed detection rate is the % of time the iCGM did not alarm when the blood glucose was at or below the alert setting within 15 minutes before and after the low glucose event.

Low Glucose Alert and Detection Rate Evaluations (Threshold only, N=110)

Alert Setting	Hypo Events (n)	Confirmed Event Detection Rate (%)	Missed Event Detection Rate (%)	Hypo Alerts (n)	True Alert Rate (%)	False Alert Rate (%)
55 mg/dL	590	76.9	23.1	952	54.5	45.5
60 mg/dL	1,275	78.2	21.8	1,487	72.0	28.0
70 mg/dL	3,053	91.4	8.6	3,274	86.7	13.3
80 mg/dL	4,667	94.0	6.0	4,936	88.8	11.2
90 mg/dL	6,477	94.0	6.0	6,436	91.7	8.3

Low Glucose Alert and Detection Rate Evaluations (Threshold and Predictive, n=110)

Alert Setting	Hypo Events (n)	Confirmed Event Detection Rate (%)	Missed Event Detection Rate %	Hypo Events (n)	True Alert Rate (%)	False Alert Rate (%)
55 mg/dL	590	88.6	11.4	1,295	51.0	49.0
60 mg/dL	1,275	90.5	9.5	1,925	66.7	33.3
70 mg/dL	3,053	96.6	3.4	3,779	81.5	18.5
80 mg/dL	4,667	97.2	2.8	5,488	84.6	15.4
90 mg/dL	6,477	97.4	2.6	7,070	88.0	12.0

High Glucose Alarm Performance

The high glucose alert rate shows how often the alert is right or wrong. The true alert rate is the % of time the iCGM alarmed when the blood glucose level was at or above the alert setting within 15 minutes before or after the iCGM alarmed (as confirmed by the comparator method). The false alert rate is the % of time the iCGM alarmed when the blood glucose level was below

the alert setting within 15 minutes before or after the iCGM alarmed. The confirmed detection rate is the % of time the iCGM alarmed when the blood glucose level was at or above the alert setting within 15 minutes before or after the hypoglycemic event. The missed detection rate is the % of time the iCGM did not alarm when the blood glucose was at or above the alert setting within 15 minutes before and after the high glucose event.

High Glucose Alert and Detection Rate Evaluations (Threshold only, N=110)

High Alert Setting (mg/dL)	Hyper Events (n)	Confirmed Event Detection Rate (%)	Missed Event Detection Rate (%)	Hyper Events (n)	True Alert Rate (%)	False Alert Rate (%)
120 mg/dL	27,247	97.6	2.4	26,866	97.5	2.5
140 mg/dL	22,520	97.4	2.6	22,253	97.2	2.8
180 mg/dL	14,874	96.4	3.6	14,720	95.5	4.5
200 mg/dL	12,150	95.3	4.7	11,845	95.4	4.6
220 mg/dL	9,762	94.5	5.5	9,376	95.3	4.7
240 mg/dL	7,728	93.7	6.3	7,371	94.5	5.5
300 mg/dL	3,010	89.6	10.4	2,945	87.8	12.2

High Glucose Alert and Detection Rate Evaluations (Threshold and Predictive, N=110)

High Alert Setting (mg/dL)	Hyper Events (n)	Confirmed Event Detection Rate (%)	Missed Event Detection Rate (%)	Hyper Events (n)	True Alert Rate (%)	False Alert Rate (%)
120 mg/dL	27,247	98.6	1.4	27,495	96.7	3.3
140 mg/dL	22,520	98.4	1.6	22,921	96.0	4.0
180 mg/dL	14,784	97.9	2.1	15,324	94.0	6.0
200 mg/dL	12,150	97.2	2.8	12,429	93.5	6.5
220 mg/dL	9,762	96.4	3.6	9,910	93.0	7.0
240 mg/dL	7,728	95.8	4.2	7,799	92.1	7.9
300 mg/dL	3,010	93.5	6.5	3,294	83.0	17.0

Sensor Stability

Sensor stability describes the performance over the sensor lifetime. Sensors can be worn for up to 365 days. Performance was estimated by calculating the percentage of Eversense 365 CGM System readings within ±15 mg/dL or 15% (15/15%), ±20 mg/dL or 20% (20/20%), or ±40 mg/dL or 40% (40/40%) of laboratory comparator values in 30-day successive intervals.

Sensor Stability Relative to Comparator (Accuracy Over Time)

Wear Period (Days)	Number of paired iCGM-Comparator	MARD	Percent within 15/15%	Percent within 20/20%	Percent within 40/40%
1-30	9,129	9.7	81.5	90.6	99.3
31-60	3,283	9.0	84.0	93.4	99.7
61-90	2,858	9.9	82.7	90.9	99.4
91-120	3,561	8.4	88.1	95.1	99.6
121-150	2,745	7.8	89.0	96.0	99.7
151-180	2,727	8.1	86.2	93.7	100.0
181-210	3,076	7.9	88.7	95.5	100.0
211-240	2,855	8.2	88.2	95.0	99.6
241-270	1,951	9.4	82.7	91.3	99.9
271-300	2,718	7.9	88.3	95.4	99.9
301-330	2,257	8.1	89.0	94.9	99.9
331-365	3,337	8.8	86.9	94.8	99.8

Sensor Life

A total of 110 Sensors were evaluated to determine the percentage of Sensors that lasted through the 365-day Sensor life.

Sensor Survival Rate by Wear (n=110)

Days since Insertion	Subjects in Study	Number of Sensors	Survival Rate (%)
1	110	107	97
30	108	105	97
60	106	103	97
90	106	102	96
120	105	101	96
150	103	99	96
180	103	99	96
210	101	96	95
240	100	95	95
270	99	92	93
300	98	90	92
330	97	89	92
365	96	86	90

The capture rate characterizes the reliability of the communication between components of the system. The Eversense 365 CGM System provides a glucose reading every 5 minutes, or up to 288 readings per day. The percentage of readings expected to be received for the system over the sensor life was evaluated from 110 sensors and is 99.9%. The table below describes the percent of readings received throughout the life span of the sensor (Capture rate).

Reading Capture Rate by Wear Day

Wear Day	Number of Sensors	Capture Rate (%)
Day 1-30	103	99.9
Day 31-60	101	99.9
Day 61-90	97	100
Day 91-120	96	99.9
Day 121-150	97	100
Day 151-180	95	100
Day 181-210	91	99.9
Day 211-240	90	100
Day 241-270	86	99.9
Day 271-300	87	99.9
Day 301-330	84	100
Day 331-365	81	99.9

Calibration Stability

A calibration study was performed after sensor insertion in which the iCGM was evaluated against the comparator.

Time from Calibration	Number of Paired iCGM-Comp data points	Percent 15/15% of Comparator	Percent 20/20% of Comparator	Percent 30/30% of Comparator	Percent 40/40% of Comparator	Percent Greater than 40/40% of Comparator
0-12 hours	10,440	85	92.7	97.9	99.3	0.7
12-24 hours	4,345	85.9	93.1	98.5	99.8	0.2
24-36 hours	1,953	87.1	95.5	99.3	99.8	0.2
36-48 hours	2,628	87	94.4	99.3	99.8	0.2
48-60 hours	1,431	86.8	94	98.9	100	0
60-72 hours	2,299	86.3	94.3	99	99.9	0.1
72-84 hours	1,465	82.9	90.5	97.7	99.4	0.6
84-96 hours	2,309	87.7	94.8	98.6	99.7	0.3
96-108 hours	1,534	86.1	93.9	98.7	99.7	0.3
108-120 hours	2,567	84.5	93.6	98.4	99.5	0.5
120-132 hours	2,095	84.8	93.1	99	99.8	0.2
132-144 hours	2,750	85.6	93.3	99	99.9	0.1
144-156 hours	1,978	83.9	93.7	99.5	100	0
156-168 hours	2,627	85.8	93.8	98.6	99.6	0.4
168-174 hours	76	86.8	96.1	97.4	100	0

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

Not applicable.

F Other Supportive Instrument Performance Characteristics Data:

Not applicable.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.