510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K251854

B Applicant

Tandem Diabetes Care

C Proprietary and Established Names

SteadiSet infusion set

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
FPA	II	21 CFR 880.5440 – Intravascular Administration Set	General Hospital

E Purpose for Submission:

Modification to a cleared device to extend the wear period to 2-7 days.

II Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The SteadiSet infusion set is indicated for the subcutaneous infusion of insulin administered by an external pump. The infusion set is indicated for single use.

C Special Conditions for Use Statement(s):

Rx – For Prescription Use Only

SteadiSet infusion set is neither intended nor indicated for use with blood, blood products, or intravenous infusion (IV).

Replace the infusion set and tubing every 2-7 days per your healthcare professional's instructions.

The infusion set should be removed if unexplained hyperglycemia is not correcting with insulin boluses, which may occur prior to the maximum wear time of 7 days.

The infusion set should be removed if there is a significant increase in total daily insulin prior to the maximum wear time of 7 days.

SteadiSet Infusion Set is a single-use device and should be disposed of immediately after use. Do not clean, re-sterilize, or re-use the set. This may cause damage to the set and may lead to infection, site irritation, or inaccurate delivery.

SteadiSet is not indicated for use in an MRI environment or during radiation therapy. Remove the infusion set prior to MRI or radiation therapy.

The SteadiSet infusion set with t:lock tubing connector should only be used with Tandem cartridges featuring the t:lock connector.

III Device Description

The device is a sterile, non-pyrogenic, intravascular administration set device used to administer insulin from a reservoir cartridge to a patient subcutaneously through a cannula. The infusion set administers insulin by means of a compatible external pump. The infusion set consists of an inserter, tube set, and disconnect cover. The inserter consists of a housing, insertion buttons, an infusion set hub (with cannula) and adhesive patch with protective liner. The inserter facilitates insertion of the cannula subcutaneously. The cannula is a soft medical-grade polymer extruded over a stainless-steel coil.

The tube set provides the insulin pathway between the hub’s indwelling cannula and an external insulin pump cartridge. The tube set consists of infusion set tubing with a reservoir connector (proximal end) and hub connector (distal end).The disconnect cover can be connected to the hub to provide cover when the infusion set tubing is disconnected from the hub.

The device is sterilized by Ethylene Oxide (ETO) and is a single-patient, single-use device to be used for up to 7 days.

IV Substantial Equivalence Information:

A Predicate Device Name(s):

SteadiSet infusion set

B Predicate 510(k) Number(s):

K242692

C Comparison with Predicate(s):

Device & Predicate Device(s):	K251854	K242692
Device Trade Name	SteadiSet infusion set	SteadiSet infusion set
General Device Characteristic Similarities		
Intended Use/Indications For Use	The SteadiSet infusion set is indicated for the subcutaneous infusion of insulin administered by an external pump. The infusion set is indicated for single use.	Same
Prescription Use	Rx required	Same
Use Type	Single use	Same
Compatible Devices	Tandem cartridges featuring the t:lock™ connector	Same
General Device Characteristic Differences		
Wear Period	2-7 days	2-3 days

V Standards/Guidance Documents Referenced:

ISO 80369-6, First Edition 2016-03-15, Small bore connectors for liquids and gases in healthcare applications – Part 6: Connectors for neuraxial applications

ISO 8536-4, Sixth edition 2019-09, Infusion equipment for medical use – Part 4: Infusion sets for single use, gravity feed.

ANSI/AAMI/ISO 14971:2019, Medical Device – Application of Risk Management to Medical Devices

ISO 10555-1, Second edition 2013-06-15, Intravascular catheters – Sterile and single-use intravascular catheters – Part 1: General requirements

ISO 10555-1, Third edition 2023-11, Intravascular catheters – Sterile and single-use intravascular catheters – Part 1: General requirements

ANSI/AAMI HE75:2009/(R)2018, Human factor engineering – Design of medical devices

IEC 62366-1, Edition 1.1 202-06, Medical devices – Part 1: Application of usability engineering to medical devices

ISO 23908, First edition 2011-06-11, Sharps injury protection – Requirements and test methods – Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling

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

ISO 11135:2014/A 1:2018, Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices – Amendment 1: Revision of Annex E. Single batch release

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

ISO 11138-1:2017, Sterilization of health care products – biological indicators – Part 1: General requirements

ANSI/AAMI ST72:2019, Bacterial endotoxins – Test methods, routine monitoring, and alternatives to batch testing

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

ISO 11608-1:2022, Needle-based injection systems for medical use – Requirements and test methods – Part 1: Needle-based injection systems

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

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

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

ASTM F1980-21, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

ASTM D4169-22, Standard Practice for Performance Testing of Shipping Containers and Systems

ASTM D4332-22, Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing

ISO 10993-1 Fifth edition 2018-08, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.

ISO 10993-2 Third edition 2022-11, Biological evaluation of medical devices – Part 2: Animal welfare

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

ISO 10993-5 Third edition 2009-06-01, Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity

ISO 10993-6 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 Third edition 2017-09, Biological evaluation of medical devices – Part 11: Tests for systemic toxicity

ISO 10993-12 Fourth Edition 2012-07-01, Biological evaluation of medical devices – Part 12: Sample preparation and reference materials

ISO 10993-12 Fifth edition 2021-01, Biological evaluation of medical devices – Part 12: Sample preparation and reference materials

ISO 10993-17 Second Edition 2023-09, Biological evaluation of medical devices – Part 17: Toxicological risk assessment of medical device constituents

ISO 10993-18 Second edition 2020-01 Amendment 1 2022-05
Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process [Including Amendment 1 (2022)]

ISO/TS 10993-19 Second edition 2020-03, Biological evaluation of medical devices – Part 19: Physico-chemical, morphological, and topographical characterization of materials

ISO 10993-23 First edition 2021-01, Biological evaluation of medical devices - Part 23: Tests for irritation

ISO/TR 10993-33 First, Biological evaluation of medical devices – Part 33: Guidance on Partial

ISO TS 21726 First edition 2019-02, Biological evaluation of medical devices – Application of the threshold of toxicological concern (TTC) for assessing biocompatibility of medical device constituents

ASTM F2503-23, Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment

ISO 15223-1 Fourth edition 2021-07, Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements

ISO 20417 First edition 2021-04 Corrected version 2021-12 Medical devices – information to be supplied by the manufacturer

VI Performance Characteristics:

A. Analytical Performance

N/A

B. Other Supportive Instrument Performance Characteristics Data

Non-clinical testing

The following testing was performed for clearance of the predicate device, K242692. This testing is being leveraged in this submission, and was determined to be adequate to demonstrate a wear period of 7 days:

1. Functional tests
    - Mechanical Integrity:
        - Cannula Pull
        - Hub Connector and Tubing Pull
        - Tubing Elongation
        - T:lock and Tubing Pull Force
    - Performance Tests:
        - Mass Flow Rate
        - Pressure Leak.
        - Tubing and Cannula Priming
        - Insertion Force and Depth
2. Usability/Human Factors
    - Simulated-Use Human Factors Validation
3. Biocompatibility
    - Cytotoxicity
    - Sensitization
    - Irritation
    - Acute Systemic Toxicity
    - Material Mediated Pyrogenicity
    - Subacute Toxicity
    - Genotoxicity
    - Implantation
    - Sub-chronic Toxicity
4. Sterilization and Shipping
    - Sterility Assurance Level 10-6
    - Shipping, Shelf-Life, and Aging Transportation Tests
5. Compatibility Tests
    - Drug and Device Compatibility
6. Shelf-Life and Aging Testing
7. Packaging
    - Free-fall drop, package sterile barrier testing, and climatic stressing and shipping testing

Clinical Testing

The sponsor conducted a clinical study to evaluate the performance of the SteadiSet insulin infusion set. For this study, the infusion set with the longest length (43 inches) was used. Subjects were instructed to change their insulin cartridge every 48-72 hours, as recommended by their healthcare provider and were instructed to change their insulin cartridge and infusion set independent of each other, following the instructions for use.

Study Feature	**Description**
Title	Open, Single-Arm, Prospective, Multicenter Study of an Investigational Extended Wear Insulin Infusion Set During Home Use in People with Type 1 Diabetes
Study Design	Prospective, Multi Center, Single Arm
Number of Sites	15 sites in the US
Population	272 adults with Type 1 Diabetes enrolled 260 subjects initiated study • 128 subjects used Humalog • 132 subjects used NovoLog 250 subjects successfully inserted • 124 subjects used Humalog • 126 subjects used NovoLog Key Inclusion Criteria • Aged 18-80 years old • Diagnosed with T1D for at least 12 months • Minimum of 6 months of insulin pump experience and 3 months of current experience with a Tandem pump • Using Tandem t:slim X2 insulin pump with Control-IQ technology for a minimum of 1 month at time of enrollment • HbA1c < 9.0% in the last 6 months Key Exclusion Criteria • Severe hypoglycemia leading to medical assistance, seizures, or loss of consciousness in the past 6 months
Study Duration	~12 weeks; 12 wear periods of up to 7 days each.
Primary Objective	The evaluation of SteadiSet device function as evidenced by the absence of device failure due to uncontrolled hyperglycemia with or without ketosis.
Primary Efficacy Endpoint	Percentage of successfully inserted SteadiSet Infusion Sets (i.e., not removed within 8 hours of insertion) that are not withdrawn from use prior to 7 days (168 hours) due to either (1), (2), or (3): 1. Blood Glucose value ≥250 mg/dL with ketones >1.0 mmol/L, in the absence of illness or other physiological stress. 2. Blood Glucose value ≥250 mg/dL for at least 60 minutes duration, 3 hours or more following a snack or meal event AND failure to

	respond to up to 2 adequate corrective boluses delivered by the pump with a fall of at least 50 mg/dL. 3. Investigator advises the infusion set should be replaced to assure participant's safety A Clinical Events Committee (CEC) adjudicated primary and key secondary clinical endpoint events based on review of all available information that was relevant to determine whether protocol-defined endpoint events occurred during the study.
Secondary Endpoints	Proportion (%) of SteadiSet Infusion Sets withdrawn from use at any time following insertion prior to 7 days (168 hours) as evidenced by one or more of the following device failure modes. NOTE: infusion set removals prior to 168 hours due to miscalculation of date and/or time, along with other removals that cannot be ascribed to the investigational device performance, are excluded from this proportion calculation. 1. Infusion set failure as defined in the Primary Endpoint (including any such removals occurring during the first 8 hours following set insertion) 2. Evidence of infusion set site infection defined as requiring treatment or at the investigator's judgment 3. Cannula dislodgement from subcutaneous (SC) space (with or without liquid leakage at the cannula insertion site) a. Leakage at the cannula insertion site may or may not be deemed by the investigator to constitute infusion set failure following consultation with the study participant b. Accidental removal events (e.g., tubing caught on doorknob) are excluded from this proportion calculation 4. Occurrence of a non-resolvable pump occlusion alarm 5. Other device malfunction (e.g., inability to pierce skin, bending, or other malformation that might impact insulin infusion, securement failure) 6. Presence of pain of sufficient severity to prompt early removal of infusion set 7. Any other event that can be ascribed to the investigational device performance that results in failure of insulin delivery
Exploratory Endpoint	HbA1c change from baseline to the end of the study participation.

Safety Endpoints	The incidence, severity, and relationship to the investigational device of all reported adverse events (serious and non-serious including diabetic ketoacidosis (DKA) and severe hypoglycemia) from day of insertion through day of device removal for each wear period.

Baseline Demographics

	Overall	**Humalog**	**NovoLog**
Number of Subjects	260	128	132
Age (years)			
Mean (standard deviation)	43.9 ± 17.3	40.9 ± 16.0	46.8 ± 18.0
Range	18 to 78	18 to 77	18 to 78
Diabetes Duration at Enrollment (years)			
Mean (standard deviation)	26.5 ± 14.3	24.5 ± 13.8	28.5 ± 14.5
Range	1 to 58	1 to 58	2 to 57
Gender			
Female [n (%)]	150 (58)	83 (65)	67 (51)
Race - [n (%)]			
White	240 (92)	115 (90)	125 (95)
Black/African America	4 (2)	3 (2)	1 (< 1)
Asian	9 (3)	7 (5)	2 (2)
More than 1 Race	6 (2)	3 (2)	3 (2)
Unknown/Not Reported	1 (< 1)	0 (0)	1 (< 1)
Hispanic Ethnicity - [n (%)]	11 (4)	4 (3)	7 (5)
Highest Level of Education - [n (%)]			
< Bachelor's Degree	68 (26)	29 (23)	39 (30)
Bachelor's Degree	125 (48)	72 (56)	53 (40)
Advanced Degree	65 (25)	27 (21)	38 (29)
Unknown/Does not wish to provide	2 (< 1)	0 (0)	2 (2)
Annual Household Income - [n (%)]			
< $50K	21 (8)	9 (7)	12 (9)
$50K to < $100K	47 (18)	25 (20)	22 (17)
≥ $100K	136 (52)	71 (55)	65 (49)
Unknown/Does not wish to provide	56 (22)	23(18)	33 (25)
Weight			
Mean (kg) (standard deviation)	77.8 ± 14.3	76.8 ± 13.9	78.8 ± 14.7
Range	43.9 to 122.8	43.9 to 113.4	53.5 to 122.8
BMI			
Mean (kg/m^2) (standard deviation)	26.6 ± 3.6	26.6 ± 3.5	26.6 ± 3.7
Range	18.9 to 34.7	20.2 to 34.3	18.9 to 34.7
Baseline HbA1c (%)			
Mean (standard deviation)	6.7 ± 0.7	6.7 ± 0.6	6.6 ± 0.7
Range	4.9 to 8.7	4.9 to 8.6	5.1 to 8.7
CGM Metrics (%) - mean ± std dev			
% time in range 70-180 mg/dL	73.0 ± 12.1	72.1 ± 12.5	73.8 ± 11.7
% time > 180 mg/dL	25.2 ± 12.7	26.2 ± 13.1	24.1 ± 12.2
% time < 70 mg/dL	1.9 ± 1.7	1.7 ± 1.5	2.0 ± 2.0
Estimated HbA1c	6.9 ± 0.7	7.0 ± 0.7	6.9 ± 0.7

Total Daily Insulin (U) Mean (standard deviation) Range	 48.1 ± 21.2 12.0 to 156.0	 48.4 ± 20.5 12.0 to 156.0	 47.9 ± 22.0 15.2 to 142.2

Safety Results

The following table shows a summary of adverse events observed during the clinical study and were used to evaluate the safety of the device. Overall, the safety data supports a finding of substantial equivalence.

Summary of Adverse Events			
	Overall N = 260 **#Events/ #Participants with ≥ 1 event**	**Humalog N = 128** **#Events/ #Participants with ≥ 1 event**	**NovoLog N = 132** **#Events/ #Participants with ≥ 1 event**
Serious Adverse Events	1/1	0/0	1/1
Severe hypoglycemia events	1/1	0/0	1/1
Diabetic ketoacidosis events	0/0	0/0	0/0
Other Serious adverse events	0/0	0/0	0/0
Adverse Events (non-serious)	55/43	20/14	35/29
Adverse Device Effect – SteadiSet Infusion Set	46/37	18/12	28/25
Set failure requiring replacement, unrelated to infusion site reaction	2/2	0/0	2/2
Infusion site reaction to inserted set	42/34	18/12	24/22
Adverse Device Effect – Tandem t:slim X2 with Control IQ Technology			
Pump failure requiring replacement	1/1	0/0	1/1
Adverse Device Effect – Dexcom G7 CGM Sensor			
Site reaction to inserted CGM sensor	1/1	0/0	1/1

Efficacy Results

Infusion Set Survival

The overall survival rate for infusion sets lasting at least 7 days, considering all possible reasons for device removal, was 78.4% (80.5% for Humalog and 76.4% for NovoLog). Possible reasons for device removal prior to 7 days included 30 sets taken out before 8 hours; 5 sets removed for an MRI or CT scan; 4 sets removed for convenience in conjunction with a cartridge change when running low on insulin; 1 set removed to avoid a set change during an upcoming trip; 1 set removed for temporary reversion to personal insulin pump after study pump malfunction; 1 set accidentally removed by participant due to confusion about study protocol; 25 sets removed at site request after participant inserted additional set beyond the maximum specified wear period per protocol (they inserted a 13th set); 3 sets removed at site request as a precaution after discovery of improper shipping procedures, and all primary, secondary, and other reasons.

Duration of Inserted Infusion Sets			
	N = 3,027* Infusion Sets Inserted	**Humalog N = 1500**	**NovoLog N = 1527**
Wear Duration (Days) Median (Q1, Q3)	7.0 (7.0, 7.0)	7.0 (7.0, 7.0)	7.0 (7.0, 7.0)
0 (0 - < 24 hours)	52 (2%)	27 (2%)	25 (2%)
1 (24 - < 48 hours)	31 (1%)	14 (<1%)	17 (1%)
2 (48 - < 72 hours)	46 (2%)	20 (1%)	26 (2%)
3 (72 - < 96 hours)	57 (2%)	25 (2%)	32 (2%)
4 (96 - < 120 hours)	111 (4%)	47 (3%)	64 (4%)
5 (120 - < 144 hours)	136 (4%)	60 (4%)	76 (5%)
6 (144 - < 168 hours)	220 (7%)	99 (7%)	121 (8%)
7 (168 - < 192 hours)	2241 (74%)	1131 (75%)	1110 (73%)
8 (182 - < 216 hours)	124 (4%)	76 (5%)	48 (2%)
9 (216 - < 240 hours)	6 (<1%)	1 (<1%)	5 (<1%)
10 (240 - < 264 hours)	1 (<1%)	0 (0%)	1 (<1%)
11 (264 - < 288 hours)	2 (<1%)	0 (0%)	2 (<1%)

The following table summarizes the descriptive summary of infusion set removals. A clinical events committee adjudicated the underlying reasons for removals and more than one cause could be selected.

Reasons for removal of infusion sets prior to 168 hours as determined by the clinical events committee			
	N = 3,027* Infusion Sets Inserted	**Humalog N = 1500**	**NovoLog N = 1527**
Primary Endpoint Criteria Met – [n (%)]	137 (4.5%)	62 (4.1%)	75 (4.9%)
Hyperglycemia and failure to respond to boluses (without ketones)	92 (3.0%)	45 (3.0%)	47 (3.1%)
Hyperglycemia with ketones > 1.0 mmol/L	24 (0.8%)	14 (0.9%)	10 (0.7%)

Investigator advised (without meeting hyperglycemia/ketone criteria)	21 (0.7%)	3 (0.2%)	18 (1.2%)
Key Secondary Endpoint Criteria Met – [n (%)]†	460 (15.2%)	195 (13.0%)	265 (17.4%)
Primary endpoint criteria met (for successful insertions)	137 (4.5%)	62 (4.1%)	75 (4.9%)
Criteria for primary endpoint met in first 8 hours after insertion	3 (0.1%)	1 (0.1%)	2 (0.1%)
Infusion set site infection requiring treatment or investigator's judgement	13 (0.4%)	6 (0.4%)	7 (0.5%)
Cannula dislodgement from subcutaneous space‡	59 (1.9%)	35 (2.3%)	24 (1.6%)
Occurance of a non-resolvable pump occlusion alarm	55 (1.8%)	12 (0.8%)	43 (2.8%)
Other device malfunction§	101 (3.3%)	51 (3.4%)	50 (3.3%)
Pain of sufficient severity to prompt early removal of infusion set	78 (2.6%)	33 (2.2%)	45 (2.9%)
Removal for unresolvable hyperglycemia or ketosis‖	214 (7.1%)	87 (5.8%)	127 (8.3%)
Other event related to infusion set resulting in failure of insulin delivery	50 (1.7%)	17 (1.1%)	33 (2.2%)
Set Removed for other reasons – [n (%)]†	193 (6.4%)	97 (6.5%)	96 (6.3%)
Early removal due to miscalculation of time/date	50 (1.7%)	25 (1.7%)	25 (1.6%)
Cannula accidentally pulled out	96 (3.2%)	49 (3.3%)	47 (3.1%)
Other reason not related to impaired insulin delivery**	51 (1.7%)	24 (1.6%)	27 (1.8%)

*During one infusion set wear, the participant switched from NovoLog to Humalog, so this wear was excluded from efficacy analyses. †When the primary endpoint criteria were not met, CEC members could specify multiple reasons for the failure of an infusion set, so the sum of the rows below is greater than the number to the right. ‡With or without liquid leakage at the cannula insertion site); not including accidental removal, such as tubing caught on doorknob. §Inability to pierce skin, bending, or other malformation that might impact insulin infusion, securement failure, or similar occurrence. ‖Hyperglycemia or ketosis not meeting criteria for primary endpoint. **This includes 23 participants who mistakenly attempted to wear a 13th set and were then asked to remove it, as well as the 3 participants at a single site who were asked to remove their set due to a site level protocol deviation.

The failure rate due to hyperglycemia, including all 3 primary endpoints and the secondary endpoint of unresolvable hyperglycemia or ketosis is given in the table below. Overall, 354 of the 3028 inserted sets (11.7%) failed for these reasons, inclusive of sets that failed within the first 8 hours of use.

Number of Failed Infusion Sets due to Primary Endpoints and Unresolvable Hyperglycemia or Ketosis									
	Overall			Humalog			NovoLog		
	N at Risk	N Failed due to Hyperglycemia	Cumulative Failure Rate	N at Risk	N Failed due to Hyperglycemia	Cumulative Failure Rate	N at Risk	N Failed due to Hyperglycemia	Cumulative Failure Rate
Day 1	3028	9	0.3%	1500	4	0.3%	1527	5	0.3%
Day 2	2976	3	0.4%	1473	0	0.3%	1502	3	0.5%
Day 3	2945	21	1.1%	1459	9	0.9%	1485	12	1.3%
Day 4	2899	30	2.1%	1439	14	1.9%	1459	16	2.4%
Day 5	2841	75	4.7%	1414	30	4.0%	1426	44	5.5%
Day 6	2731	96	8.1%	1367	45	7.1%	1364	52	9.1%
Day 7	2594	120	12.4%	1307	48	10.6%	1286	72	14.2%

Glycemic Control Metrics

CGM outcomes were tabulated by day of infusion set wear, including all infusion sets with a minimum of 20 hours of wear. The average time in range at baseline was 73% ± 12.1%, increased to 75.3% ± 10.1% over the first 72 hours of wear, and decreased to 67.8% ± 13.0% over hours 72-168 of wear. The mean glucose (mg/dL) was 152.7 ± 20.2 at baseline, decreased to 147.7 ± 16.9 over the first 72 hours of wear, and increased to 163.0 ± 20.5 over hours 72-168 of wear.

	N	**% Time in Range 70-180 mg/dL**	**% Time in Tight Range 70-140 mg/dL**	**Mean Glucose (mg/dL)**	**% Time > 180 mg/dL**	**% Time > 250 mg/dL**	**% Time < 70 mg/dL**	**% Time < 54 mg/dL**	**CGM Hyper-glycemic Event Rate per week[a]**	**CGM Hypo-glycemic Event Rate per week[b]**
Baseline	260	73.0% ± 12.1%	47.6% ± 14.0%	152.7 ± 20.2	25.2% ± 12.7%	6.4% ± 6.5%	1.9% ± 1.7%	0.4% ± 0.5%	1.6 ± 1.8	0.8 ± 1.1
Day 1	2892	73.6% ± 15.2%	50.3% ± 16.9%	148.4 ± 23.4	23.5% ± 15.1%	6.1% ± 8.3%	2.9% ± 4.0%	0.7% ± 1.8%	1.7 ± 3.5	1.3 ± 3.6
Day 2	2850	77.3% ± 14.8%	51.7% ± 18.3%	145.3 ± 22.1	20.5% ± 14.9%	4.0% ± 6.8%	2.2% ± 3.4%	0.5% ± 1.4%	0.9 ± 2.5	0.9 ± 3.0
Day 3	2809	75.4% ± 16.2%	49.2% ± 19.2%	149.0 ± 24.0	22.7% ± 16.5%	4.7% ± 7.7%	1.9% ± 3.2%	0.4% ± 1.2%	1.1 ± 2.8	0.8 ± 2.8

Day 4	2750	72.8% ± 17.6%	44.7% ± 20.2%	154.8 ± 26.5	25.8% ± 18.0%	5.8% ± 9.3%	1.4% ± 2.6%	0.3% ± 1.0%	1.4 ± 3.3	0.6 ± 2.3
Day 5	2669	69.0% ± 19.3%	40.2% ± 20.7%	161.2 ± 29.1	29.9% ± 19.7%	7.5% ± 11.0%	1.1% ± 2.4%	0.2% ± 1.0%	1.8 ± 3.5	0.5 ± 2.2
Day 6	2536	66.6% ± 20.7%	37.1% ± 21.2%	165.2 ± 30.3	32.5% ± 21.0%	8.2% ± 11.4%	0.9% ± 2.3%	0.2% ± 0.9%	1.9 ± 3.7	0.4 ± 2.1
Day 7	2351	64.4% ± 21.1%	34.1% ± 21.1%	168.2 ± 30.1	34.7% ± 21.5%	8.7% ± 11.4%	8.7% ± 11.4%	0.2% ± 0.9%	2.2 ± 3.9	0.4 ± 1.9

a. A CGM-measured prolonged hyperglycemic event is defined as at least 2 sensor values >250 mg/dL that are 120 or more minutes apart plus no intervening values ≤250 mg/dL; at least 2 sensor values ≤180 mg/dL that are 15 or more minutes apart with no intervening values >180 mg/dL are required to define the end of an event, at which point the study participant becomes eligible for a new event.
b. A CGM-measured hypoglycemic event <54 mg/dL is defined as at least 2 sensor values <54 mg/dL that are 15 or more minutes apart plus no intervening values ≥54 mg/dL; at least 2 sensor values ≥54 mg/dL that are 15 or more minutes apart with no intervening values <54 mg/dL are required to define the end of an event, at which point the study participant becomes eligible for a new event.

Insulin outcomes were also tabulated by day of infusion set wear. Overall, total daily insulin needs increased from 49.1 ± 23.3 units/day on Day 1 to 57.7 ± 26.7 units/day on Day 7.

	N	**Total Daily Insulin (U)**	**Basal (U)**	**Bolus (U)**	**Bolus/Basal**
Baseline	260	48.1 ± 21.2	22.8 ± 10.5	25.3 ± 13.9	1.2 ± 0.6
Day 1	2971	49.1 ± 23.3	22.5 ± 10.8	26.6 ± 15.8	1.3 ± 0.7
Day 2	2942	47.3 ± 22.2	22.4 ± 10.5	24.9 ± 15.1	1.2 ± 0.7
Day 3	2900	48.5 ± 23.7	23.0 ± 11.2	25.6 ± 15.7	1.2 ± 0.7
Day 4	2846	51.0 ± 24.5	24.0 ± 11.6	27.0 ± 16.3	1.2 ± 0.7
Day 5	2751	53.9 ± 26.0	25.2 ± 12.0	28.7 ± 17.7	1.2 ± 0.7
Day 6	2625	56.2 ± 26.8	26.4 ± 12.7	29.8 ± 17.9	1.2 ± 0.7
Day 7	2434	57.7 ± 26.7	27.4 ± 13.1	30.3 ± 17.7	1.2 ± 0.7

The overall change in HbA1c for the study period, as well as an analysis of changes in HbA1c by average infusion set wear length, are shown in the tables below.

	Baseline N = 260	**Final Visit N = 256**	**95% Confidence Interval [P-value]**
HbA1c (%) – mean ± SD	6.7 ± 0.7	6.8 ± 0.7	0.08 (0.04, 0.12) [< 0.001]

	Baseline		Final Visit		Change from Baseline	
	N	Mean ± SD	N	Mean ± SD	N	Mean ± SD
Overall						
Average set wear length (days)						
< 3	1	7.1	1	7.2	1	0.1
3 - < 5	6	6.6 ± 0.9	6	6.9 ± 1.0	6	0.28 ± 0.48
5 - < 7	125	6.8 ± 0.7	122	6.8 ± 0.6	122	0.06 ± 0.32
≥ 7	128	6.6 ± 0.6	127	6.7 ± 0.7	127	0.08 ± 0.34
Humalog						
Average set wear length (days)						
< 3	1	7.1	1	7.2	1	0.10
3 - < 5	2	7.3 ± 1.2	2	7.2 ± 1.0	2	-0.05 ± 0.21
5 - < 7	59	6.7 ± 0.6	58	6.8 ± 0.7	58	0.08 ± 0.35
≥ 7	66	6.7 ± 0.7	66	6.8 ± 0.7	66	0.09 ± 0.39
NovoLog						
Average set wear length (days)						
< 3	0	-	0	-	0	-
3 - < 5	4	6.2 ± 0.6	4	6.7 ± 1.1	4	0.45 ± 0.51
5 - < 7	66	6.8 ± 0.7	64	6.8 ± 0.6	64	0.04 ± 0.28
≥ 7	62	6.5 ± 0.6	61	6.5 ± 0.6	61	0.07 ± 0.28

Discussion of Clinical Study Results

Past day 3 of the study, results showed trends towards decreasing time in range, increasing time above range, increasing mean glucose, and increasing total daily dose of insulin use on average for the study participants over the duration of the device wear period during this 12-week clinical study.

The overall change in HbA1c observed from baseline to the end of the 12-week study was an increase of 0.1 and was not considered to be clinically significant. An additional analysis of HbA1c change for study participants that had average infusion set wear durations of at least 7 days or less than 7 days did not show a clear correlation between increasing average infusion set wear time and worsening HbA1c. Average observed change in HbA1c was zero for subjects who averaged less than 7 days of wear per infusion set, and an increase of 0.1 for subjects who averaged at least 7 days of wear. This difference was not considered to be clinically significant.

The overall standard deviation in HbA1c change from baseline for study participants was 0.7. As with other aspects of diabetes management and insulin therapy, individualization of device use may be appropriate. The recommended duration of device use is between 2 to 7 days, which allows for patients and their healthcare providers to individualize device use as needed based on real world use.

VII Proposed Labeling:

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

VIII Conclusion:

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