



510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION DECISION SUMMARY

I Background Information:

A 510(k) Number

K260429

B Applicant

Tandem Diabetes Care, Inc.

C Proprietary and Established Names

Control-IQ+ technology

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
QJI	Class II	21 CFR 862.1356	CH – Clinical Chemistry

E Purpose for Submission:

The purpose of this submission is to expand the indications for use to include pregnancy complicated by type 1 diabetes mellitus.

II Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

Control-IQ+ technology is intended for use with compatible integrated continuous glucose monitors (iCGM) and alternate controller enabled (ACE) pumps to automatically increase, decrease, and suspend delivery of basal insulin based on iCGM readings and predicted glucose values. It can also deliver correction boluses when the glucose value is predicted to exceed a predefined threshold.

Control-IQ+ technology is intended for the management of Type 1 diabetes mellitus in persons 2 years of age and greater and of Type 2 diabetes mellitus in persons 18 years of age and greater.

Control-IQ+ technology is intended for use in pregnancy complicated by Type 1 diabetes mellitus, provided the linked CGM system is suitable for use in pregnancy.

Control-IQ+ technology is intended for single patient use and requires a prescription.

C Special Conditions for Use Statement(s):

Rx – For Prescription Use Only

Pregnant users should only utilize this System with a CGM that is suitable for use during pregnancy.

Only use U-100 insulin analogs that have been tested and found to be compatible for use in the pump. Use of insulin with lesser or greater concentration can result in under delivery or over delivery of insulin. This can cause hypoglycemia (low BG) or hyperglycemia (high BG) events.

When the CGM reading is automatically populated into the bolus calculator, only the current CGM reading is used to calculate the correction bolus. The trend arrow is not used in the dose calculation. Speak with your healthcare provider for recommendations on how best to utilize the arrows for your correction bolus dosing.

Control-IQ+ should not be used in anyone under the age of two years old. Control-IQ+ should also not be used in patients who require less than a total daily insulin dose of 5 units per day or who weigh less than 20 pounds, as those are the required minimum values needed in order for Control-IQ technology to operate safely.

The pump is magnetic resonance (MR) unsafe. You must take off your pump and leave it outside the procedure room.

DO NOT use Dexcom CGM readings to make diabetes treatment decisions or assess glucose control when taking hydroxyurea, a medication used in the treatment of diseases including cancer and sickle cell anemia. Hydroxyurea is known to interfere with glucose readings from the Dexcom sensor. Relying on sensor glucose values while taking hydroxyurea could result in missed hypoglycemia alerts or errors in diabetes management, such as giving a higher dose of insulin than necessary to correct falsely high sensor glucose values.

III Device Description

The Subject Device, Control-IQ+ technology (“Control-IQ+”) is a software-only device intended for the management of type 1 and type 2 diabetes mellitus. The device controls insulin delivery from a compatible alternate controller enabled insulin pump (ACE pump) based on inputs provided by a compatible integrated continuous glucose monitor (iCGM) and inputs provided by the user (e.g., carbohydrate intake, exercise, and sleep schedule). Control-IQ+ technology is meant to be installed on a compatible ACE pump.

Control-IQ+ technology has three different modes: Normal, Sleep, and Exercise. The glucose targets are not individually customizable in these modes but can change based on the mode selected. During Normal mode, Control-IQ+ technology aims to control glucose within a target

range of 112.5 – 160 mg/dL, during Sleep mode the target range is 112.5 – 120 mg/dL, and during Exercise mode the target range is 140 – 160 mg/dL.

Control-IQ+ technology includes an integrated feature whereby iCGM values are automatically populated into the glucose field of the integrated bolus calculator when Control-IQ+ technology is active (i.e., the device is operating in closed-loop mode). This feature is disabled when Control-IQ+ is turned off.

Control-IQ+ technology requires users to input their weight and their total daily insulin requirement, which should be established with the help of a health care provider before using the device.

IV Substantial Equivalence Information:

A Predicate Device Name(s):

Control-IQ+ technology

B Predicate 510(k) Number(s):

K250798

C Comparison with Predicate(s):

Device & Predicate Device(s):	<u>K260429</u>	<u>K250798</u>
Device Trade Name	Control-IQ+ technology	Same
General Device Characteristic Similarities		
Intended Use/Indications For Use	Control-IQ+ technology is intended for use with compatible integrated continuous glucose monitors (iCGM) and alternate controller enabled (ACE) pumps to automatically increase, decrease, and suspend delivery of basal insulin based on iCGM readings and predicted glucose values. It can also deliver correction boluses when the glucose value is predicted to exceed a predefined threshold.	Same

	Control-IQ+ technology is intended for single patient use and requires a prescription.	
General Device Characteristic Differences		
Intended Use Population	Control-IQ+ technology is intended for the management of Type 1 diabetes mellitus in persons 2 years of age and greater and of Type 2 diabetes mellitus in persons 18 years of age and greater. Control-IQ+ technology is intended for use in pregnancy complicated by Type 1 diabetes mellitus, provided the linked CGM system is suitable for use in pregnancy.	Control-IQ+ technology is intended for the management of Type 1 diabetes mellitus in persons 2 years of age and greater and of Type 2 diabetes mellitus in persons 18 years of age and greater.

V Standards/Guidance Documents Referenced:

- Special controls established under 21 CFR 862.1356
- ANSI AAMI ISO 14971:2019 Medical devices – Applications of risk management to medical devices

VI Performance Characteristics:

A. Non-Clinical Performance

Non-clinical performance was not applicable to the modifications made in this submission.

B. Clinical Studies

For the evaluation of Control-IQ+ technology in a clinical study, Control-IQ technology was installed on the t:slim X2 insulin pump with interoperable technology and paired with the Dexcom G6 iCGM. The clinical study was conducted in Canada and Australia, and the Dexcom G6 was approved for use during pregnancy in Canada for the majority of the time the study was active and in Australia for the duration of the clinical study. Most Dexcom G6 sensors were worn on the back of the upper arm. Some subjects chose to wear sensors in other locations, including the abdomen, lower back, and leg. The differences in performance between the Dexcom G6 (not cleared for use in the U.S. during pregnancy) and the Dexcom G7 are not expected to result in significantly different clinical outcomes.

Control-IQ technology does not have a pregnancy-specific design and in this study, it was adapted for use during pregnancy. Adaptations included using the device for the majority of time in sleep mode (target glucose 112.5 – 120 mg/dL) and adjusting basal rates, insulin to

carbohydrate ratios, and correction factors, generally making them more aggressive over time throughout pregnancy.

A total of 91 subjects were enrolled in this study, 46 in the intervention group and 45 in the standard care group. During the study, 6 subjects in the intervention group and 3 subjects in the standard care group used U-200 insulin. Since U-200 insulin products are not approved for use in insulin pumps in the U.S., the description of the demographics and results from the study, in the tables below, includes data only from participants who used U-100 insulin exclusively in the study. Two subjects began using U-200 insulin during week 34. For U-200 insulin users, transition back to U-100 insulin use occurred after delivery. Clinical outcomes were not significantly different between U-100 and U-200 users and conclusions from the study are unaffected by removal of the U-200 subjects from the analysis.

Summary of Clinical Testing

The CIRCUIT (Closed-loop Insulin delivery by glucose Responsive Computer algorithms in Type 1 diabetes pregnancies) clinical study was conducted to evaluate the Control-IQ technology in pregnant women with type 1 diabetes.

Study Feature	Description
Title	Closed-loop Insulin delivery by glucose Responsive Computer algorithms In Type 1 diabetes pregnancies (CIRCUIT)
Study Design	A parallel arm, open-label, multi-center, randomized controlled trial of pregnant women with pre-existing type 1 diabetes
Number of Sites	15 total sites; 14 sites enrolled subjects • 10 sites in Canada; 9 sites enrolled subjects • 5 sites in Australia
Population	Pregnant women with type 1 diabetes were enrolled before 14 weeks gestation and followed until 6-weeks postpartum. Participants were randomized 1:1 to an intervention group or control group. • N = 46 in the intervention group: t:slim X2 insulin pump with Control-IQ technology and Dexcom G6 CGM (closed-loop group) • N=45 in the standard care group: continuation of pre-study insulin delivery method, plus use of the Dexcom G6 CGM (standard care group) 88 women completed the study through 6 weeks after delivery. 9 of the 88 participants who completed the study (6 in the intervention arm and 3 in the standard care arm) used U-200 insulin at some point during the study. Those participants have been excluded from the summary tables below.

	Key Inclusion Criteria • Aged 18-45 years (inclusive) • A diagnosis of type 1 diabetes, as defined by Diabetes Canada, for at least 12 months • Currently on insulin therapy (≥ 3 injections or CSII) • HbA1c $\geq 6.2\%$ and $< 10\%$, measured any time during pregnancy prior to enrollment Key Exclusion Criteria • Current treatment with drugs known to interfere with glucose metabolism, such as high dose synthetic corticosteroids • Total daily dose of insulin < 8 or > 250 units/day at screening • Current use of Tandem Control-IQ, DIY looping system, 670G in Auto Mode, or alternate closed-loop system
Protocol Overview/Synopsis	After consent was signed and participants were enrolled, participants continued to use their personal insulin delivery method (pump or MDI) during a 1-week Dexcom CGM run-in. Participants who completed the CGM run-in by 15 weeks gestation were then randomized 1:1 to either their current insulin modality + CGM (standard care group) or the Tandem t:slim X2 insulin pump with Control-IQ technology (intervention group), and started closed-loop use (if required) by 15 weeks + 6-7 days. Follow-up visits occurred at 16 weeks ± 7 days, 20 weeks ± 7 days, 24 weeks ± 7 days, 28 weeks ± 7 days, 32 weeks ± 7 days, 34 weeks ± 7 days, 36 weeks ± 7 days, and 6 weeks postpartum. HbA1c was recorded at enrollment, 24 weeks, and 34 weeks. It was also recorded at 6 weeks postpartum, if the subject had it collected during a standard of care visit in the timeframe of ± 2 weeks of study visit. Questionnaires were completed at Visit 1 (enrollment, 7-13 weeks 6 days gestation), Visit 5 (24 weeks gestation), Visit 8 (34 weeks gestation), and Visit 11 (6 weeks postpartum). The partner questionnaire was also completed at the same visits if the partner consented to participate.
Primary Endpoint	The primary efficacy endpoint defined by the sponsor for the study was the glycemic control as reflected by percent glucose time in range (63-140 mg/dL) per day assessed by CGM glucose measurement (16 weeks until 34 weeks 6 days

	gestation) compared between intervention and standard care groups. FDA's assessment of clinical study results was primarily based on results through the end of pregnancy and through 6 weeks postpartum.
Safety Results	No unexpected device-related safety issues occurred during pregnancy. Considering only subjects who used U-100 insulin during the study, there were 2 episodes of diabetic ketoacidosis in the intervention group and 1 in the standard care group. There were no severe hypoglycemia events in the intervention group and 1 in the standard care group. There were 2 miscarriages in the intervention group that were not attributed to device use.

Device Use During the Study (N = 79 subjects, excluding those who used U-200 insulin at any point during the study)

During the CIRCUIT study, 32 of 38 subjects who were randomized into the Control-IQ arm used Control-IQ for more than 90% of the time and median was 94.7%.

Frequency of Closed-Loop System Use in the Control-IQ Group (n = 38)	
Median [IQR]	94.7 [92.3, 95.7]
> 90%	32
80 – 90%	5
70 – 80%	0
60 – 70%	0
50 – 60%	0
< 50%	1 used closed-loop for 1 week
0%	0

Subjects were advised to use the device in sleep mode (target glucose 112.5 – 120 mg/dL) throughout the day and night. From the start of pump use through delivery, subjects used sleep mode 84.4% of time, compared to 11.7% of the time in normal mode and 3.9% of the time in exercise mode. The time spent in sleep mode decreased in the 7 days after delivery to 52.6%. The table below shows the fraction of time spent in each mode from starting device use through 6 weeks postpartum.

Percent of Time Spent in Different Activity Modes in Control-IQ Arm			
	Pump Start to Delivery	Delivery to 7 days Postpartum	Delivery to 6 Weeks Postpartum
Normal Mode (SD)	11.7 (18.3)	42.8 (44.4)	38.2 (40.1)
Exercise Mode (SD)	3.9 (16.4)	4.6 (19.1)	9.4 (23.5)
Sleep Mode (SD)	84.4 (23.0)	52.6 (44.1)	52.5 (40.0)

Healthcare providers in the study also advised subjects to adjust their basal rate settings through pregnancy so that the programmed total basal settings were at least equal to the average total basal insulin use for the previous 1-2 weeks. After 20 weeks gestation, subjects

were advised by their providers to program their total daily basal rate settings to be 20% more than the average total basal used in the previous 1-2 weeks.

Providers also recommended that study subjects strengthen the correction factor to be at least as strong as 1620 mg/dL divided by the average total daily insulin dose in the previous 1-2 weeks. They recommended that carb ratios should be individualized but ratios at least as strong as 400 divided by the total daily insulin dose should be considered. Carb ratios/mealtime insulin doses were also strengthened as needed as pregnancy progressed beyond 20 weeks gestation. Subjects in both study arms were instructed by providers in the study to bolus 10-15 minutes before meals in the first trimester, 20-30 minutes before meals in the second trimester, and 30-45 minutes before meals in the third trimester. Both study arms also received guidance to make diet adjustments that may include meals consisting of higher fiber carbohydrates with protein to reduce the rise in blood sugar after meals, in addition to smaller snacks throughout the day to limit the amount of carbohydrate eaten during meals. Weight and total daily dose settings were not routinely updated in Control-IQ during pregnancy.

Study subjects did not enter carbs above what they were eating (i.e., “ghost carbs” were not used). If subjects wanted to manually request additional insulin, they used the built in functions of the Control-IQ system to request additional insulin correction, and if necessary to manually override the recommended insulin dose to request additional insulin. The use of manual overrides to meal boluses was rare (e.g., <1% of meal boluses), and there were no pregnancy-specific instructions provided to subjects on the use of this feature.

The study protocol included 11 scheduled visits with study staff, including visits for enrollment, randomization, delivery, 6 weeks postpartum, and 7 visits from week 16 gestation to week 36 gestation (weeks 16, 20, 24, 28, 32, 34, and 36). Nearly every study visit was completed in both arms of the study, except for missed visits due to miscarriage or early delivery before 36 weeks.

Study subjects had frequent contact with their medical clinic, with a mean of 19 contacts per participant in both arms of the study. There were 60 unscheduled research contacts in the Control-IQ group and 32 unscheduled research contacts in the Standard Care group. The reasons for regular clinic contacts and unscheduled research contacts in the Control-IQ arm were due to questions or issues regarding the devices or needing supplies and in the Standard Care arm were due to questions related to the CGM or supplies.

Participant Demographics (N = 79 subjects, excluding those who used U-200 insulin at any point during the study)

Characteristic	Closed-Loop n = 38	Standard Care n = 41
Age (yrs) Mean ± SD	31.6 ± 5	31.6 ± 5
Race and Ethnicity – no. (%) ^a		
European or Mediterranean	32 (87)	32 (78)
Indigenous	2 (5)	2 (5)
South Asian	1 (3)	2 (5)
Other	2 (5)	5 (12)

Duration of diabetes – years Median [IQR]	20.4 [13.9, 25.9]	19.5 [15.2, 24.1]
BMI (kg/m²) Mean ± SD	27.5 ± 4.7	28.4 ± 4.3
Education Primary education (age 5-11) Secondary education (age 11-17) Trade/technical school degree University undergraduate degree University higher degree	1 (2.6) 5 (13.2) 12 (31.6) 11 (28.9) 9 (23.7)	0 (0) 9 (22.0) 8 (19.5) 14 (34.1) 10 (24.4)
Week of gestation At enrollment, mean ± SD At randomization, mean ± SD At closed-loop initiation, mean ± SD	11.0 ± 2.0 12.5 ± 2.0 13.3 ± 1.6	10.9 ± 1.7 12.2 ± 1.7 NA
Pregnancy History Primiparous – no. (%) Previous pregnancy loss – no. (%) ^b Pre-pregnancy factors – no. (%) • Folic acid supplementation • Alcohol consumption (current preg.) • Cigarette smoking (current preg.) • Preconception care ^c	13 (34.2) 15 (39.5) 23 (60.5) 4 (10.5) 3 (7.9) 19 (50.0)	12 (29.3) 13 (31.7) 26 (63.4) 5 (12.2) 2 (4.9) 18 (43.9)
Glycated hemoglobin level (%) during early pregnancy 6.2 to < 6.5 – no. (%) 6.5 to < 7.0 – no. (%) 7.0 to < 7.5 – no. (%) 7.5 to < 8.0 – no. (%) ≥ 8.0 to 10 – no. (%) Mean HbA1c ± SD Range	2 (5.3) 16 (42.1) 9 (23.7) 4 (10.5) 7 (18.4) 7.29 ± 0.96 6.2 – 9.6	3 (7.3) 14 (34.1) 9 (22.0) 4 (9.8) 11 (26.8) 7.47 ± 1.01 6.3 – 9.6
Using CGM prior to study – no. (%) All brands Dexcom Medtronic Abbott	32 (84.2) 19 (50.0) 1 (2.6) 12 (31.6)	37 (90.2) 13 (31.7) 5 (12.2) 19 (46.3)
Insulin delivery – no. (%) Multiple daily injections Insulin pump (open-loop)	19 (50.0) 19 (50.0)	21 (51.2) 20 (48.8)
Total daily insulin – units/day Mean ± SD	47.4 ± 17.5	51.5 ± 22.3
Total daily insulin – units/kg/day Mean ± SD	0.6 ± 0.2	0.7 0.6 ± 0.2 0.2

^aParticipants self-reported race on a fixed category questionnaire with an optional write-in answer. For the Closed-Loop group, 37 participants reported results, where other race or ethnicity groups included 1 participant who self-identified as East Asian and 1 who self-identified as Jewish. For the Standard Care group, 41 participants reported results, where 2 self-identified as Black, 2 as Middle Eastern, and 1 as multiethnic.

^bPregnancy losses include previous miscarriages and previous terminations.

^cPreconception care means that participants were seen in a diabetes in pregnancy clinic prior to pregnancy.

Overall Glycemic Outcomes (*N* = 79 subjects, excluding those who used U-200 insulin at any point during the study)

Glycemic control as reflected by percent glucose time in range (63-140 mg/dL) per day assessed by CGM glucose measurement (16 weeks until end of pregnancy) was compared between Control-IQ and Standard Care groups. For subjects who only used U-100 insulin during the study, the mean time in pregnancy-specific glucose range (63-140 mg/dL) increased from 55.5% at baseline to 67.2% in the Control-IQ arm and from 48.4% at baseline to 51.8% in the Standard Care arm from 16 weeks to end of pregnancy. The adjusted group difference [Control-IQ minus Standard Care] was 12.6 percentage points (95% CI 9.4, 15.9); $p < 0.001$) higher in the Control-IQ group. The results presented in the table below show the glycemic control from baseline to end of pregnancy.

Outcome	Baseline		Intervention (16 weeks to end of pregnancy)		Adjusted Treatment Difference (95% CI)
	Control-IQ (n = 38)	Standard Care (n = 41)	Control-IQ (n = 38)	Standard Care (n = 41)	
% time in glucose range 63-140 mg/dL	55 ± 11.1	48.4 ± 15.9	67.2 ± 8.9	51.8 ± 13.3	12.6 (9.4, 15.9)
% time in glucose range < 63 mg/dL	3.4 ± 3.5	2.9 ± 3.2	1.2 ± 1.0	2.1 ± 1.8	-1.1 (-1.6, -0.6)
% time in glucose range > 140 mg/dL	41.1 ± 12.6	48.7 ± 16.3	31.6 ± 8.9	46.0 ± 14.0	-11.3 (-14.6, -7.9)
Mean glucose level (mg/dL)	139.4 ± 18.8	152.1 ± 30.1	130.0 ± 9.2	146.3 ± 22.1	-9.1 (-13.6, -4.6)
Glucose SD (mg/dL)	51.5 ± 11.6	56.2 ± 13.6	38.9 ± 6.7	51.7 ± 12.2	-9.9 (-12.7, -7.1)
Glucose coefficient of variation %	37.0 ± 6.2	36.9 ± 5.6	29.8 ± 3.7	35.1 ± 4.2	-5.3 (-6.6, -4.0)

Intrapartum and Postpartum Glycemic Outcomes (*excluding those who used U-200 insulin at any point during the study*)

During intrapartum and postpartum periods, subjects dealt with the challenges of laboring and breastfeeding. 34 of the 38 subjects continued to use their pump through delivery. Two subjects were not allowed to continue closed-loop therapy during their Caesarean deliveries due to hospital policy, one subject stopped closed-loop therapy 11 days prior to delivery, and one subject stopped closed-loop therapy 1 week after initiating it in pregnancy because of infusion site pain. Subjects who used the device in the 24-hour period leading up to delivery had 79.3% time in pregnancy-specific glucose range (63-140 mg/dL) compared to 63.6% of

subjects in the standard care group. At 1 week postpartum, the Control-IQ arm had 86.2% time in range (70-180 mg/dL) compared to 74.3% in the Standard Care arm, and from delivery to 6 weeks postpartum, the Control-IQ arm had 83.3% time in range compared to 65.1% in the Standard Care arm.

	Control-IQ	Standard Care	Adjusted Treatment Difference (95% CI)
24 hours up to delivery			
n	34	39	
% time in glucose range 63-140 mg/dL	79.3 ± 14.9	63.6 ± 19.8	13.4 (5.1, 21.7)
% time in glucose range < 63 mg/dL	1.0 ± 1.8	1.1 ± 2.1	-0.1 (-1.0, 0.7)
% time in glucose range > 140 mg/dL	19.7 ± 14.4	35.3 ± 19.7	-13.1 (-21.3, -5)
Mean glucose level (mg/dL)	118.2 ± 11.9	130.5 ± 20.4	-9.2 (-17.1, -1.3)
Glucose SD (mg/dL)	29.5 ± 12.5	34.7 ± 10.9	-3.9 (-9.4, 1.6)
Glucose coefficient of variation %	24.6 ± 9.0	26.3 ± 5.9	-1.1 (-4.4, 2.2)
First Week Postpartum			
n	34	40	
% time in glucose range 70-180 mg/dL	86.2 ± 7.1	74.3 ± 14.0	10.5 (5.3, 15.6)
% time in glucose range < 70 mg/dL	1.5 ± 1.8	3.3 ± 2.3	-2.2 (-3.1, -1.3)
% time in glucose range > 180 mg/dL	12.3 ± 7.5	22.4 ± 14.4	-8.2 (-13.6, -2.8)
Mean glucose level (mg/dL)	134.6 ± 13.7	146.3 ± 21.9	-7.9 (-16.1, 0.4)
Glucose SD (mg/dL)	38.2 ± 7.9	50.6 ± 14.2	-10.6 (-15.8, -5.4)
Glucose coefficient of variation %	28.4 ± 4.9	34.3 ± 6.6	-5.9 (-8.6, -3.2)
From Delivery to 6 Weeks Postpartum			
n	34	40	
% time in glucose range 70-180 mg/dL	83.3 ± 5.1	65.1 ± 13.9	12 (7.9, 16.2)
% time in glucose range < 70 mg/dL	1.4 ± 1.1	2.9 ± 2.0	-1.6 (-2.2, -1.0)
% time in glucose range > 180 mg/dL	15.3 ± 5.5	32.0 ± 14.2	-10.2 (-14.4, -5.9)
Mean glucose level (mg/dL)	139.5 ± 9.1	162.6 ± 24.8	-16.6 (-21.3, -12.0)
Glucose SD (mg/dL)	41.2 ± 6.0	61.1 ± 14.5	-17.1 (-21.4, -12.8)
Glucose coefficient of variation %	29.5 ± 3.8	37.2 ± 5.2	-7.6 (-9.6, -5.7)

HbA1c Outcomes (*N* = 79 subjects, excluding those who used U-200 insulin at any point during the study)

For subjects who only used U-100 insulin during the study, the HbA1c decreased from 7.3% at baseline to 5.9% at 24 ± 4 weeks gestation and to 6.2% at 34 weeks ± 4 weeks gestation in the Control-IQ arm and from 7.5% at baseline to 6.5% at 24 weeks ± 4 weeks gestation and to 6.6% at 34 weeks ± 4 weeks gestation in the Standard Care arm.

	Baseline		Intervention (24 weeks ± 4 gestational weeks gestation)		Adjusted Treatment Difference (95% CI)
	Control-IQ (n = 38)	Standard Care (n = 41)	Control-IQ (n = 38)	Standard Care (n = 41)	
HbA1c (%)	7.3 ± 0.9	7.5 ± 1.0	5.9 ± 0.5	6.5 ± 0.9	-0.5 (-0.7, -0.2)
	Baseline		Intervention (34 weeks ± 4 gestational weeks gestation)		Adjusted Treatment Difference (95% CI)
	Control-IQ (n = 38)	Control-IQ (n = 38)	Control-IQ (n = 38)	Standard Care (n = 41)	
HbA1c (%)	7.3 ± 0.9	7.5 ± 1.0	6.2 ± 0.5	6.6 ± 0.9	-0.3 (-0.6, -0.1)

Safety Results (*N* = 82 subjects, excluding those who used U-200 insulin at any point during the study)

Adverse events were recorded after randomization through 6 weeks postpartum for all subjects. The table below provides the types of adverse events by treatment arm (n = 82) post-randomization through 6 weeks postpartum, excluding the 9 participants who used U-200 insulin during the study.

	Number of Events	
	Control-IQ (n = 40 randomized participants)	Standard Care (n = 42 randomized participants)
Total number of adverse events	47	56
Severe Hypoglycemia (SH) Events ^a	0	1
Diabetic Ketoacidosis (DKA) Events ^b	2	1
Other Serious Adverse Events (SAES)	1	7
Anaphylaxis	0	1
Endometritis from retained placenta	0	1
Headache	1	0
Nausea and Vomiting	0	1
Perianal abscess	0	1
Persistent episiotomy wound infection	0	1
Pneumonia/Influenza A	0	1

Viral gastroenteritis	0	1
Non-serious Adverse Events		
Hyperglycemia with or without Ketosis Related to Study Device	1	0
Hyperglycemia with or without Ketosis Not Related to Study Device	3	0
Hypoglycemia (non-severe)	1	0
Other reported adverse events	39	47

^a A severe hypoglycemic event is defined as a hypoglycemic event that a) required assistance of another person due to altered consciousness, and b) required another person to actively administer carbohydrate, glucagon, or other resuscitative actions. One episode occurred in the Standard Care group 12 days postpartum.

^b DKA events meeting DCCT criteria.

Maternal and Neonatal Outcomes

Maternal outcomes, including rates of Cesarean delivery, maternal weight gain, and new or worsening hypertension were not significantly different between the intervention and standard care arms. Neonatal outcomes, including small or large for gestational age, shoulder dystocia, hypoglycemia treated with dextrose hyperbilirubinemia, or neonatal intensive care ≥ 1 day were also not significantly different between the intervention and standard care arms. Overall, the maternal and neonatal outcomes were similar in both groups but favored the intervention group using Control-IQ.

C. Other Supportive Device Performance Characteristics Data

Human Factors

Human factors validation studies were provided in K2423823, K232382, K200467, and DEN190034. No differences in critical tasks were identified between adults with type 1 diabetes and pregnant women with type 1 diabetes. People with type 1 diabetes do not face new critical tasks or perform new critical tasks with this device as a result of their pregnancy status. Device use during the clinical study was generally the same as how it is currently used on the market, and adaptations that were recommended during the clinical study are part of normal device use.

Software

The Control-IQ+ technology in this submission does not include any software changes compared to the predicate device, Control-IQ+ technology (K250798). The ACE pump software versions 7.4.3 and 7.6 (cleared in K232382) and Control-IQ (cleared in K200467) were used in the CIRCUIT study. However, when this device is marketed, it will be for ACE pump software version 7.10.3 and Control-IQ+ (first cleared K232382). The main difference in the iAGC from the prior versions of the pump to the latest ACE pump software version 7.10.3 is the addition of the Control-IQ+ feature set. The differences between Control-IQ and Control IQ+ have not changed since it was integrated into the ACE pump software beginning with version pump software version 7.9. Differences between Control-IQ and Control-IQ+ include allowed minimum and maximum weight and total daily insulin, correction factor range, maximum extended bolus duration, and basal rate clipping. These differences did not affect the use of this device during the CIRCUIT clinical study.

Cybersecurity

The Control-IQ+ technology in this submission does not include any changes to the Software, Firmware, Cybersecurity & Interoperability compared to the predicate device Control-IQ+ technology (K250798). Additionally, there are no significant alterations to the design of security controls or the operational functionality of Control-IQ+ technology in comparison to the predicate device Control-IQ+ technology (K250798).

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.