



510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION DECISION SUMMARY

I Background Information:

A 510(k) Number

K243823

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 - Interoperable Automated Glycemic Controller	CH - Clinical Chemistry

E Purpose for Submission:

The purpose of this submission is an expansion of the indications for use (IFU) to include type 2 diabetes mellitus in persons 18 years of age and greater.

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 single patient use and requires a prescription.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

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 System is magnetic resonance (MR) unsafe. You must take off your pump, transmitter, and sensor and leave them outside the procedure room.

DO NOT use Control-IQ+ if you are taking hydroxyurea, a medication used in the treatment of diseases including cancer and sickle cell anemia. Your Dexcom G6 CGM readings may be falsely elevated and result in over-delivery of insulin that could result in severe hypoglycemia.

III Device/System Characteristics:

Control-IQ+ technology (Control-IQ+, the device) 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, this range is changed to 112.5-120 mg/dL, and it is changed to 140-160 mg/dL during exercise mode.

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):

K232382

C Comparison with Predicate(s):

Device & Predicate Device(s):	<u>K243823</u>	<u>K232382</u>
Device Trade Name	Control-IQ+ technology	Control-IQ technology
General Device Characteristic Similarities		
Intended Use/Indications For Use	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
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 the management of Type 1 diabetes mellitus in persons 2 years of age and greater.

V Standards/Guidance Documents Referenced:

Special controls established under 21 CFR 862.1356.

ISO 14971:2007: Medical Devices - Application of Risk Management to Medical Devices FDA Recognition No: 5-40

IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION, Medical devices - Part 1: Application of usability engineering to medical devices

VI Performance Characteristics (if/when applicable):

A Analytical Performance:

For the purposes of analytical and clinical validation testing, the Control-IQ algorithm was installed on the t:slim X2 Insulin Pump with Interoperable Technology ACE pump (K232380), which was paired with the Dexcom G6 continuous glucose monitoring system (K223931).

B Other Supportive Instrument Performance Characteristics Data:

Summary of Clinical Testing:

The sponsor conducted a prospective, multi-center, randomized controlled study to compare the use of Control-IQ+ technology (or automated insulin dosing (AID) group) to the use of a continuous glucose monitor (CGM) with basal-bolus insulin therapy (or CGM group). The randomized controlled phase (Primary Study) was 13 weeks in duration.

A summary of the pivotal clinical study is provided in the following table (Control-IQ+ technology group abbreviated as AID):

Study Feature	Description
Title	A Randomized Trial Evaluating the Efficacy and Safety of Control-IQ Technology in Adults with Type 2 Diabetes Using Basal-Bolus Insulin Therapy (2IQP)
Summary	Randomized controlled trial in adults with type 2 diabetes comparing the use of Tandem t:slim X2 insulin pump with Control-IQ+ technology and Dexcom G6 (AID treatment group) in adults with type 2 diabetes on basal-bolus insulin versus continued care with Dexcom G6 (CGM control group).
Investigational Device	t:slim X2 insulin pump with Control-IQ+ technology
Objectives	The objective of the study is to assess efficacy and safety of a closed loop system (Control-IQ+ technology) in adults with type 2 diabetes in a randomized controlled trial.

Study Design	Randomized Clinical Trial with 2:1 randomization to intervention with the closed loop system vs. sensor-augmented basal-bolus insulin delivery for 13 - 17 weeks.
Number of Sites	21 clinical sites (19 in the United States, 2 in Canada).
Population	<p>There were 319 subjects ages 19 to 87, diabetes duration 1 to 59 years, and baseline HbA1c 5.2% to 14.1% (mean 8.2±1.3%).</p> <p>Key Inclusion Criteria:</p> <ul style="list-style-type: none"> • Clinical diagnosis of type 2 diabetes of at least 6 months • Using basal-bolus insulin therapy or an insulin pump for at least 3 months • If using noninsulin glucose lowering medications, dose stable for prior 3 months <p>Key Exclusion Criteria:</p> <ul style="list-style-type: none"> • Current use of hybrid closed-loop system • Use of systemic glucocorticoids, sulfonylurea or hydroxyurea
Sample Size	319 participants completed the randomized trial, with 215 in the intervention arm and 104 in the control arm.
Treatment Groups	<p>Randomized Trial</p> <ul style="list-style-type: none"> • Intervention Group: t:slim X2 with Control-IQ+ technology and Dexcom G6 iCGM. • Control Group: Basal-Bolus insulin with Dexcom G6 iCGM.
Study Duration	13 to 17 weeks depending on participation in run-in period.

Protocol Overview/Synopsis	<p>After consent was signed, eligibility was assessed. Eligible participants not currently using a Dexcom G6 continuous glucose monitor (CGM), or not meeting CGM usage requirements, initiated a run-in phase of 3 to 4 weeks that was customized based on whether the participant was already a CGM user. Participants continued to use their personal insulin delivery method (pump or MDI) during the CGM Run-in.</p> <p>Participants who skipped or successfully completed the run-in were randomly assigned 2:1 to an intervention group using t:slim X2 insulin pump with Control-IQ+ technology and CGM (AID group) or the control group using the continuation of pre-study basal-bolus insulin delivery method in conjunction with study CGM (CGM group).</p> <p>At randomization and the 13-week visit, a blood sample was obtained for central lab HbA1c determination. At screening and at the 13-week visit, patient reported outcomes were completed. Participants in the AID group were asked to perform 3 meal challenges and (if found to be medically eligible) 3 exercise challenges.</p>
Safety Results	<p>There was 1 severe hypoglycemia event during the study period but it was unclear if it was attributable to the device. The subject was able to treat this appropriately at home.</p> <p>There were no other severe hypoglycemia or diabetic ketoacidosis events during the study. There were 25 serious adverse events not related or unlikely to be related to the study device or treatments.</p>

Participant Demographics

	AID Group N = 215	CGM Group N = 104
Age (years)		
Mean \pm SD	59 \pm 12	57 \pm 12
Range	19 to 87	23 to 80
Sex – Female n (%)	105 (49%)	49 (47%)
Weight (kg)		
Median (IQR)	99 (84, 117)	103 (0.6, 1.2)
Range	49 to 164	0.2 to 3.6
BMI (kg/m²)		
Median (IQR)	33 (29, 40)	35 (29, 40)
Range	19 to 56	20 to 57

Race		
White	148 (69%)	74 (71%)
Black / African American	45 (21%)	24 (23%)
Asian	10 (5%)	3 (3%)
Native Hawaiian / Other Pacific Islanders	2 (<1%)	0 (0%)
American Indian / Alaskan Native	1 (<1%)	1 (<1%)
More than one race	6 (3%)	2 (2%)
Unknown / Not reported	3 (1%)	0 (0%)
Ethnicity		
Hispanic or Latino	23 (11%)	11 (11%)
Non-Hispanic or Latino	190 (88%)	93 (89%)
Unknown/not reported	2 (<1%)	0 (0%)
Education		
< High School Diploma	8 (4%)	3 (3%)
High School Diploma / GED	57 (27%)	21 (20%)
Technical/Vocational	25 (12%)	12 (12%)
Associate Degree	33 (15%)	16 (15%)
College Graduate	49 (23%)	32 (31%)
Advanced Degree	33 (15%)	16 (15%)
Unknown	1 (<1%)	0 (0%)
Do not wish to provide	9 (4%)	4 (4%)
Annual Household Income		
<\$50,000	60 (28%)	26 (25%)
\$50,000-<\$100,000	52 (24%)	21 (20%)
\$100,000 or more	53 (25%)	36 (35%)
Unknown	11 (5%)	5 (5%)
Does not wish to report	39 (18%)	16 (15%)
Health Insurance		
Private	116 (54%)	65 (63%)
Medicare	57 (27%)	15 (14%)
Medicaid	10 (5%)	13 (13%)
Other government insurance	23 (11%)	8 (8%)
No coverage	2 (<1%)	2 (2%)
Unknown / No answer	7 (3%)	1 (<1%)

Participant Diabetes History

	A1D Group N = 215	CGM Group N = 104
Diabetes Duration (yrs)		
<5	11 (5%)	9 (9%)
5-<10	31 (15%)	10 (10%)
10-<20	71 (42%)	39 (38%)
≥20	102 (38%)	46 (44%)
Median (IQR)	18 (11, 24)	18 (11, 24)
Range	1 to 59	2 to 45
Insulin Modality		
MDI	206 (96%)	100 (96%)

Pump	9 (4%)	4 (4%)
Insulin		
Insulin pump with rapid acting analog	9 (4%)	4 (4%)
Once daily basal insulin with rapid acting analog multiple times per day	156 (73%)	74 (71%)
Once daily basal insulin with regular insulin multiple times per day	2 (<1%)	0
Twice daily U-500 with or without a rapid acting analog multiple times per day	2 (<1%)	0
Twice daily basal insulin with a rapid acting analog multiple times per day	36 (17%)	21 (20%)
Twice daily basal insulin with regular insulin multiple times per day	5 (2%)	4 (4%)
Twice daily premixed insulin	5 (2%)	1 (<1%)
Non-Insulin Glucose Lowering Medications n (%)		
Metformin	109 (51%)	61 (59%)
SGLT-2 inhibitor	76 (35%)	41 (39%)
GLP-1 agonist	87 (40%)	54 (52%)
SGLT-2 inhibitor and GLP-1 Agonist	44 (20%)	24 (23%)
Other ^a	9 (4%)	10 (10%)
Prior Continuous Glucose Monitor Use		
Current	147 (68%)	78 (75%)
In past, but not current	40 (19%)	16 (15%)
Never	28 (13%)	10 (10%)
HbA1c – Local at enrollment		
<7.0%	28 (13%)	15 (14%)
7.0% to <8.0%	73 (34%)	40 (38%)
8.0% to <9.0%	66 (31%)	24 (23%)
≥9.0%	47 (22%)	25 (24%)
Mean (SD)	8.2 (1.4)	8.1 (1.2)
Range	5.7 to 14.1	5.2 to 12.4
Total Daily Insulin (units/kg/day)		
Median (IQR)	0.9 (0.6, 1.2)	0.9 (0.6, 1.2)
Range	0.2 to 2.7	0.2 to 3.6
Severe Events prior 12 months		
Severe hypoglycemia ever	5 (2%)	3 (3%)
Diabetic ketoacidosis ever	4 (2%)	2 (2%)
Hyperosmolar hyperglycemic state ever	0	1 (<1%)
c-Peptide^b (nmol/L) – Median (IQR)	0.76 (0.46, 1.2)	0.86 (0.50, 1.3)
GAD Antibody (IU/mL) – n (%)		
<5.0	202 (94%)	92 (88%)
5.0 to <250	3 (1%)	8 (8%)
≥250	10 (5%)	4 (4%)

a - Other medications included alogliptin, linagliptin, pioglitazone, and sitagliptin

b - For c-Peptide, 0.007 is lab's detectable limit

Observed Results

The primary endpoint evaluated the non-inferiority of the change in HbA1c at baseline to the end of 13 weeks between the intervention group (AID group) and control group (CGM group). HbA1c changed from $8.2 \pm 1.4\%$ at randomization to $7.3 \pm 0.9\%$ at 13 weeks in the AID group, compared to $8.1 \pm 1.2\%$ at randomization to $7.7 \pm 1.1\%$ at 13 weeks for the CGM group. The AID group had a 13-week adjusted group difference from the CGM group of -0.6% with a 95% confidence interval of -0.8% , -0.4% .

HbA1c group comparison

	AID group	CGM Group
Baseline (n)	n=214 ^a	n=104
Baseline mean HbA1c (SD)	8.2% (1.4%)	8.1% (1.2%)
13 weeks (n)	n=209 ^b	n=102 ^c
13 weeks mean HbA1c (SD)	7.3% (0.9%)	7.7% (1.1%)
Change from Baseline mean HbA1c	-0.9% (1.1%)	-0.3% (0.9%)
13 week Adjusted Group Difference (95% CI)^d [p-value]	-0.6% (-0.8%, -0.4%) [<0.001]	

a – missing (sample not analyzable) for one participant

b – Four participants dropped prior to 13 weeks final visit. The sample for one participant not analyzable. The sample for one participant was collected outside the pre-specified analysis window and thus not included.

c – Two participants dropped prior to 13 weeks final visit.

d – The difference is AID group – CGM group. Direct likelihood was used to handle missing data. The model adjusted for the baseline HbA1c and for site as a random effect.

A key secondary endpoint evaluated the non-inferiority of the change in CGM time in range (70 – 180 mg/dL) at baseline to the end of 13 weeks between the intervention group (AID group) and control group (CGM group). CGM time in range changed from $48 \pm 24\%$ at randomization to $64 \pm 16\%$ at 13 weeks in the AID group, compared to $51 \pm 21\%$ at randomization to $52 \pm 21\%$ at 13 weeks for the CGM group. The AID group had a 13-week adjusted group difference from the CGM group of 14% with a 95% confidence interval of 11% , 17% .

CGM percent time in range (70 – 180 mg/dL) group comparison

	AID Group	CGM Group
Baseline mean (SD)	48% (24%)	51% (21%)
13 weeks mean (SD)	64% (16%)	52% (21%)
Change from Baseline mean (SD)	16% (19%)	1% (14%)
13-week Adjusted^a Group Difference (95% CI) [p-value]	14% (11%, 17%) [<0.001]	

a – The model adjusted for the baseline HbA1c and for site as a random effect.

Subgroup analyses support that improvement in HbA1c after 13 weeks of AID use were seen across the AID group and were greater than from the CGM group and were similar across the distribution of age, sex, racial or ethnic minorities, diabetes duration, baseline bolus method, and prior insulin regimen. The table below depicts HbA1c and (SD). N values correspond to week 13.

Subgroup analysis of change in HbA1c over 13 weeks

	AID			CGM		
	N	Baseline mean % (SD)	Change from Baseline mean % (SD)	N	Baseline mean % (SD)	Change from Baseline mean % (SD)
Overall	208	8.2 (1.4)	-0.9 (1.1)	102	8.0 (1.1)	-0.3 (0.9)
Baseline lab HbA1c						
<7.0%	28	6.4 (0.4)	-0.0 (0.4)	15	6.5 (0.4)	0.0 (0.4)
7.0% to <8.0%	71	7.5 (0.3)	-0.5 (0.6)	40	7.5 (0.3)	-0.1 (0.6)
8.0% to <9.0%	65	8.4 (0.3)	-0.9 (0.7)	24	8.3 (0.3)	-0.2 (0.8)
>9.0%	44	10.3 (1.2)	-2.3 (1.2)	23	9.7 (0.6)	-1.0 (1.1)
Baseline time in range (70-180 mg/dL)						
>60%	79	7.4 (0.9)	-0.4 (0.8)	39	7.3 (0.7)	-0.2 (0.7)
30% to <60%	77	8.2 (0.9)	-0.8 (0.8)	44	8.1 (0.9)	-0.2 (0.9)
<30%	52	9.5 (1.5)	-2.0 (1.2)	19	9.4 (0.8)	-0.6 (1.0)
Non-insulin glucose lowering medications						
None	46	8.7 (1.7)	-1.4 (1.3)	12	8.7 (1.1)	-0.4 (1.4)
Other, but no SGLT-2i or GLP-1ra	48	8.3 (1.5)	-1.0 (1.2)	20	8.3 (1.0)	-0.3 (0.9)
GLP-1ra, but no SGLT-2i	42	8.1 (1.3)	-0.8 (0.9)	29	7.8 (1.1)	-0.4 (0.8)
SGLT-2i, but no GLP-1ra	29	8.2 (0.9)	-0.7 (0.8)	17	7.8 (1.2)	-0.3 (0.7)
Both GLP-1ra and SGLT-2i	43	7.9 (1.1)	-0.8 (1.0)	24	7.8 (1.1)	-0.1 (0.7)
BMI (kg/m²)						
<30	58	8.3 (1.6)	-0.9 (1.2)	30	8.2 (1.1)	-0.5 (1.0)
30 to <35	71	8.3 (1.3)	-1.0 (1.1)	24	8.3 (1.2)	-0.5 (0.9)
35 to <40	32	7.9 (0.9)	-0.8 (0.7)	26	7.7 (1.2)	-0.2 (0.4)
>40	47	8.3 (1.5)	-1.0 (1.1)	22	7.9 (0.9)	0.0 (0.8)
Total daily insulin (units/day)						
<100	125	8.3 (1.5)	-1.0 (1.1)	57	7.9 (1.0)	-0.3 (0.7)
100 to <150	55	8.1 (1.1)	-0.9 (1.0)	27	8.2 (1.3)	-0.3 (0.8)
150 to <200	14	8.0 (0.8)	-0.6 (0.7)	12	7.7 (0.8)	0.2 (1.0)
>200	14	7.9 (1.3)	-0.9 (1.2)	6	8.7 (1.7)	-1.0 (1.4)
Sex						
Female	100	8.4 (1.5)	-1.0 (1.2)	48	8.0 (1.1)	-0.4 (1.0)
Male	108	8.0 (1.2)	-0.8 (1.0)	54	8.0 (1.1)	-0.2 (0.7)
Age at enrollment (years)						
<50	48	8.7 (1.7)	-1.5 (1.4)	29	8.2 (1.4)	-0.2 (1.0)
50 to <65	83	8.3 (1.3)	-1.0 (1.1)	48	8.0 (1.0)	-0.4 (0.9)
>65	77	7.8 (1.0)	-0.6 (0.7)	25	7.9 (1.0)	-0.2 (0.6)
Diabetes duration at enrollment (years)						
<5	10	8.5 (1.6)	-1.3 (1.3)	9	8.3 (0.6)	-0.3 (1.3)

5 to <10	29	8.5 (1.3)	-1.3 (1.1)	10	8.4 (1.4)	-0.6 (1.3)
10 to <20	69	8.2 (1.5)	-0.9 (1.2)	38	8.1 (1.1)	-0.2 (0.8)
>20	100	8.1 (1.2)	-0.8 (1.0)	45	7.8 (1.2)	-0.3 (0.7)
Race/ethnicity						
White non-Hispanic	125	8.0 (1.3)	-0.9 (1.0)	65	7.9 (1.0)	-0.1 (0.7)
Other	82	8.6 (1.4)	-1.0 (1.2)	37	8.2 (1.3)	-0.6 (1.0)
Using a form of fixed dosing to calculate meal boluses (based on screening visit CRF)						
Yes	158	8.2 (1.4)	-0.9 (1.1)	75	8.1 (1.0)	-0.3 (0.8)
No	50	8.2 (1.3)	-1.0 (1.1)	27	7.9 (1.4)	-0.4 (1.1)
C-peptide (nmol/L)						
<0.8	108	8.3 (1.2)	-1.0 (1.1)	46	8.3 (1.2)	-0.3 (0.9)
>0.8	100	8.2 (1.5)	-0.9(1.1)	55	7.8 (1.0)	-0.3 (0.8)
Score on the subjective numeracy survey						
<4.5	89	8.2 (1.3)	-0.9 (1.0)	43	8.1 (1.2)	-0.3 (0.8)
>4.5	119	8.2 (1.5)	-1.0 (1.1)	59	8.0 (1.1)	-0.3 (0.9)
Insulin modality prior to enrollment						
MDI	199	8.2 (1.4)	-0.9(1.1)	98	8.0 (1.1)	-0.3 (0.9)
Pump	9	8.1 (0.9)	-1.0 (0.9)	4	8.2 (1.1)	-0.3 (0.3)
CGM user prior to enrollment						
Yes	141	8.1 (1.3)	-0.8 (1.0)	77	7.9 (1.1)	-0.2 (0.6)
No	67	8.5 (1.5)	-1.2 (1.2)	25	8.5 (1.1)	-0.6 (1.3)

Subgroup analysis of key secondary endpoint CGM metrics for the AID and CGM groups after 13 weeks support similar effects for CGM time in range (TIR; 70 – 180 mg/dL), time below range (TBR; <70 mg/dL) and time above range (TAR; >180 mg/dL) across the distribution of age, sex, racial or ethnic minorities, diabetes duration, baseline bolus method, and prior insulin regimen. The table below depicts percent of time within range and (SD). N values correspond to the baseline.

Subgroup analysis of change in CGM metrics for A1D group after 13 weeks

	N	Time Below 70mg/dL		Time in Range 70-180 mg/dL		Time Above 180mg/dL	
		Baseline mean % (SD)	Change from Baseline mean % (SD)	Baseline mean % (SD)	Change from Baseline mean % (SD)	Baseline mean % (SD)	Change from Baseline mean % (SD)
Overall	214	0.7 (1.4)	-0.2 (1.2)	48 (24)	16 (19)	51 (25)	-16 (19)
Baseline lab HbA1c							
<7.0%	28	1.2 (2.3)	-0.5 (1.9)	78 (15)	3 (11)	21 (15)	-2 (11)
7.0% to <8.0%	72	0.7 (1.4)	-0.3 (1.3)	58 (18)	10 (14)	41 (18)	-9 (15)
8.0% to <9.0%	66	0.6 (1.4)	-0.2 (1.0)	41 (18)	21 (19)	58 (19)	-21 (19)
≥9.0%	47	0.4 (0.9)	-0.1 (0.8)	25 (18)	27 (21)	75 (18)	-27 (21)
Baseline time in range 70-180 mg/dL							
≥60%	79	1.2 (1.9)	-0.5 (1.7)	74 (11)	2 (9)	25 (11)	-1 (10)
30% to <60%	80	0.6 (1.2)	-0.2 (0.9)	45 (9)	16 (14)	54 (9)	-16 (14)
<30%	55	0.1 (0.1)	0.1 (0.3)	16 (9)	37 (15)	84 (9)	-37 (15)
Non-insulin glucose lowering medications							
None	46	0.7 (1.2)	-0.1 (1.2)	41 (22)	22 (17)	59 (22)	-22 (18)
Other, but no SGLT-2i or GLP-1ra	50	0.9 (1.9)	-0.4 (1.5)	47 (24)	17 (19)	53 (25)	-17 (20)
GLP-1ra, but no SGLT-2i	43	0.5 (1.3)	-0.2 (0.8)	48 (26)	13 (20)	51 (27)	-13 (20)
SGLT-2i, but no GLP-1ra	31	0.9 (1.9)	-0.6 (1.6)	52 (24)	11 (19)	47 (25)	-10 (19)

Both GLP-1ra and SGLT-2i	44	0.4 (0.7)	0.1 (0.7)	55 (24)	15 (18)	45 (25)	-15 (18)
BMI (kg/m²)							
<30	59	0.7 (1.6)	-0.3 (1.4)	47 (27)	16 (21)	53 (27)	-16 (22)
30 to <35	72	0.7 (1.1)	-0.2 (1.1)	48 (24)	17 (19)	51 (24)	-17 (19)
35 to <40	34	0.7 (2.0)	-0.2 (1.4)	49 (23)	16 (18)	50 (24)	-16 (18)
≥40	49	0.6 (1.4)	-0.2 (1.1)	50 (24)	15 (16)	50 (24)	-15 (16)
Total daily insulin (units/day)							
<100	128	0.6 (1.4)	-0.2 (1.2)	46 (26)	18 (20)	54 (26)	-18 (21)
100 to <150	57	0.8 (1.7)	-0.3 (1.3)	52 (22)	14 (16)	48 (22)	-13 (16)
150 to <200	15	0.6 (0.9)	-0.2 (0.7)	48 (23)	16 (17)	52 (23)	-16 (17)
≥200	14	0.9 (1.2)	-0.2 (0.9)	58 (23)	12 (15)	41 (24)	-11 (16)
Sex							
Female	105	0.5 (0.9)	-0.1 (1.0)	46 (24)	17 (18)	53 (24)	-17 (19)
Male	109	0.9 (1.8)	-0.4 (1.4)	50 (25)	16 (19)	49 (25)	-15 (20)
Age at enrollment (years)							
<50	50	0.5 (1.2)	-0.2 (1.1)	41 (26)	22 (19)	59 (27)	-22 (19)
50 to <65	86	0.6 (1.4)	-0.2 (1.3)	47 (25)	16 (20)	52 (26)	-16 (21)
≥65	78	0.8 (1.6)	-0.2 (1.2)	54 (21)	12 (16)	45 (21)	-12 (16)
Diabetes duration at enrollment (years)							
<5	11	1.0 (2.1)	-0.6 (1.8)	41 (30)	26 (19)	58 (31)	-25 (20)
5 to <10	31	0.6 (1.0)	-0.3 (0.8)	45 (21)	18 (17)	54 (21)	-18 (18)
10 to <20	71	0.7 (1.8)	-0.3 (1.5)	47 (25)	16 (20)	52 (25)	-16 (20)
≥20	101	0.6 (1.2)	-0.1 (1.0)	50 (25)	14 (18)	49 (25)	-14 (19)

Race/ethnicity							
White non-Hispanic	129	0.6 (1.3)	-0.2 (1.2)	51 (26)	16 (18)	48 (26)	-16 (18)
Other	84	0.8 (1.6)	-0.3 (1.3)	43 (21)	18 (20)	56 (22)	-17 (20)
Using a form of fixed dosing to calculate meal boluses (based on screening visit CRF)							
Yes	161	0.8 (1.6)	-0.3 (1.4)	49 (24)	15 (19)	50 (25)	-15 (20)
No	53	0.3 (0.6)	-0.0 (0.4)	45 (24)	20 (17)	55 (25)	-20 (17)
C-peptide (nmol/L)							
<0.8	112	0.8 (1.4)	-0.3 (1.3)	49 (23)	14 (18)	50 (23)	-14 (19)
≥0.8	102	0.5 (1.5)	-0.2 (1.1)	47 (26)	18 (19)	53 (27)	-18 (19)
Score on the subjective numeracy survey							
<4.5	91	0.7 (1.3)	-0.1 (1.1)	49 (24)	15 (19)	51 (25)	-15 (19)
≥4.5	123	0.7 (1.5)	-0.3 (1.2)	48 (25)	17 (19)	52 (25)	-17 (19)
Insulin modality prior to enrollment							
MDI	205	0.7 (1.5)	-0.2 (1.2)	48 (24)	16 (19)	51 (25)	-16 (19)
Pump	9	0.4 (0.8)	-0.1 (0.4)	44 (24)	21 (19)	56 (24)	-20 (19)
CGM user prior to enrollment							
Yes	146	0.6 (1.4)	-0.2 (1.2)	48 (24)	17 (17)	52 (24)	-17 (18)
No	68	0.8 (1.4)	-0.3 (1.3)	49 (26)	14 (22)	50 (27)	-14 (22)

Challenge Results

During this clinical study, subjects in the AID group participated in 3 meal challenges and 3 exercise challenges.

From the AID group 195 participants completed 567 meal challenges in which no bolus, half bolus or full bolus was delivered. Of the meal challenges 320 were lunch meals, 209 were dinner meals and 38 were meals outside of lunch or dinner. The median amount of carbohydrates was 60 grams. During and up to the 4 hours post the meal challenge the CGM time in range increased from 57% to 66% to 71% for no bolus, half bolus and full bolus respectively.

From the AID group 172 participants completed 511, 60-minute-long exercise challenges, of which 500 were intensity of mild or moderate. During and for 2 hours after the exercise challenge there was minimal (less than 0.01%) of time below 70 mg/dL as determined by CGM.

Summary of Human Factors Validation Study

The study was conducted as established in K232382. No differences in critical tasks were identified between adults with type 1 diabetes (T1D) and adults with type 2 diabetes (T2D). A summative Human Factors validation was performed and followed FDA recognized standard IEC 62366-1 as well as the FDA guidance document *Applying Human Factors and Usability Engineering to Medical Devices* (February 3, 2016). A summative validation study evaluated a total of 30 individuals with T2D to ensure individuals can safely and effectively perform critical tasks associated with the use of Control-IQ+ technology.

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.