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

I Background Information:

A 510(k) Number

K202145

B Applicant

Bigfoot Biomedical, Inc.

C Proprietary and Established Names

Bigfoot Unity Diabetes Management System

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
QLG	Class II	21 CFR 862.1355 – Integrated Continuous Glucose Monitoring System	CH – Clinical Chemistry
QOG	Class II	21 CFR 880.5860 – Injection Data Capture Device	General Hospital

II Submission/Device Overview:

A Purpose for Submission:

New device

B Measurand:

Glucose in interstitial fluid

C Type of Test:

Quantitative, amperometric assay (Glucose Oxidase)

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The Bigfoot Unity Diabetes Management System is indicated for the management of diabetes in persons age 12 years and older.

Bigfoot Unity provides glucose monitoring data via the Abbott FreeStyle Libre 2 Flash Glucose Monitoring sensor. The system incorporates real time alarm capabilities and is designed to replace blood glucose testing for diabetes treatment decisions, unless otherwise indicated. The device is intended to provide insulin dose information using the available glucose data to assist persons with diabetes mellitus who use disposable pen-injectors for the self-injection of insulin in implementing health care provider recommended insulin dose regimens. The device is intended for single patient use only and requires a prescription.

Bigfoot Unity is also intended to communicate autonomously with digitally connected medical devices where the user manually controls therapy decisions.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

The System must not be used with automated insulin dosing (AID) systems, including closed loop and insulin suspend systems.

Taking ascorbic acid (Vitamin C) supplements while wearing the Sensor may falsely raise Sensor glucose readings. You can take doses of ascorbic acid up to 500 mg per day and make treatment decisions with the Sensor. Taking more than 500 mg of ascorbic acid per day may affect the Sensor readings which could cause you to miss a severe low glucose event.

The System must be removed prior to Magnetic Resonance Imaging (MRI), Computed Tomography (CT) scan, or high-frequency electrical heat (diathermy) treatment. The effect of MRI, CT scans, or diathermy on the performance of the System has not been evaluated. The exposure may damage the Sensor and may impact proper function of the device which could cause incorrect readings.

Do not use the System in people less than 12 years of age.

Do not use this system if you are pregnant, on dialysis, or critically ill. The System is not cleared for use in these groups and it is not known how different conditions or medications common to these populations may affect performance of the System.

Performance of the System has not been evaluated when used with other implaneted medical devices, such as pacemakers.

The System does not support insulin doses in half-increments. Patients who require half-unit doses of insulin should not use the System.

The System supports once daily dosing of long-acting insulin. Patients who take more than one daily dose of long-acting insulin should not use the System.

Do not ignore symptoms that may be due to low or high blood glucose: if you are experiencing symptoms that are not consistent with the glucose readings, consult your health care professional.

Use your blood glucose meter to make diabetes treatment decisions when you see the "check blood glucose" symbol during the first 12 hours of wearing a Sensor, if your Sensor glucose reading does not match how you feel, or if the reading does not include a number.

Wash application site on the back of your upper arm using a plain soap, dry, and then clean with an alcohol wipe. This will hep remove any oily residue that may prevent the sensor from sticking properly. Allow site to air dry before proceeding. Carefully preparing the site according to these instructions will help the Sensor stay on your body for the full 14-day wear period and help prevent it from falling off early.

Store the Sensor Kit between 36°F and 82°F. If you suspect that the temperature may exceeed 82°F (e.g., an un-airconditioned home in the summer), you should refridgerate your Sensor Kit. Do not freeze your Sensor Kit.

You must scan the Sensor to get your current glucose level as the Bigfoot Unity App will not provide this information.

Take standard precautions for transmission of blood borne pathogens to avoid contamination.

Use of the Sensor with devices, apps, and software that are not listed by the manufacturer as compatible with the System may cause inaccuracte glucose readings.

If a Sensor breaks inside your body, call your health care professional.

D Special Instrument Requirements:

N/A

IV Device/System Characteristics:

A Device Description:

The Bigfoot Unity utilizes continuous glucose monitoring to support people with diabetes mellitus who use disposable insulin pens for self-injection of insulin. The system consists of the Abbott FreeStyle Libre 2 integrated continuous glucose monitor (iCGM), two reusable insulin pen caps (one each for rapid-acting and long-acting insulin pens) and a mobile application. The components communicate via near field communication (NFC) and Bluetooth Low Energy (BLE).

The Bigfoot Unity contains a digital lookup table that displays insulin dose recommendations on the Bigfoot Unity pen caps based on healthcare provider (HCP)-prescribed regimens. The System also provides a set of meal dose recommendations based on meal size, where the meal doses are set by the HCP and entered in the lookup table.

The device generates glucose data using the FreeStyle Libre 2 sensor and displays the data (value and trend) on the rapid-acting insulin pen cap (the White Cap) when the user scans the sensor using the White Cap. The rapid-acting pen cap also displays correction and meal insulin doses based upon the lookup table and available glucose data. The long-acting pen cap (the Black Cap) displays the long-acting insulin dose prescribed by the user's healthcare provider. From the dose recommendations on the pen caps, as well as other contextually relevant information such as glucose trend arrows, users manually select an insulin dose and administer it using the pens according to the insulin manufacturers' instructions. In addition to displaying dose information, both pen caps track the time of insulin doses.

The mobile app allows user entry, in consultation with their HCP, of a prescribed insulin dosing regimen into the digital lookup table, as well as provides system alerts and historical information. The mobile app has a built-in, mandatory low-glucose alarm at 55 md/dL and an optional low-glucose alarm at 70 mg/dL. The mobile app receives glucose data from the sensor via BLE and will alert if the sensor glucose reading is below the threshold(s). However, in order to obtain the glucose sensor value, the user must scan the sensor with the White Cap. Additionally, the mobile app manages the secure wireless communication between the system components and enables the transfer of the system data to the cloud.

B Principle of Operation:

Bigfoot Unity incorporates the FreeStyle Libre 2 continuous glucose sensor and glucose translation library for calculating glucose values and trend information. Additionally, Bigfoot Unity uses the FreeStyle Libre 2 wireless communication protocols to (1) obtain glucose values and trend information on the White Cap, and (2) provide real-time alerts in the mobile app.

C Instrument Description Information:

1. Instrument Name:

   Bigfoot Unity

2. Specimen Identification:

   N/A

3. Specimen Sampling and Handling:

   N/A

4. Calibration:

   The sensor is factory calibrated and does not require calibration from the user/operator.

5. Quality Control:

N/A

V *Substantial Equivalence Information:*

A Predicate Device Name(s):
FreeStyle Libre 2 Flash Glucose Monitoring System

B Predicate 510(k) Number(s):
K193371

C Comparison with Predicate(s):

Device & Predicate Device(s):	K202145	K193371
Device Trade Name	Bigfoot Unity Diabetes Management System	FreeStyle Libre 2 Flash Glucose Monitoring System
General Device Characteristic Similarities		
Intended Use/Indications For Use	The Bigfoot Unity Diabetes Management System provides glucose monitoring data via the Abbott FreeStyle Libre 2 Flash Glucose Monitoring sensor. The system incorporates real time alarm capabilities and is designed to replace blood glucose testing for diabetes treatment decisions, unless otherwise indicated.	Same
Primary Principle of Operation	Amperometric measurement of current proportional to glucose concentration in interstitial fluid via glucose oxidase chemical reaction.	Same
Sample Type	Interstitial fluid	Same
Enzyme	Glucose oxidase	Same
Clinical Setting/Sites of Use	Home use	Same

Glucose Trend Arrow	↑, more than +2 mg/dL/min ↗, +1 and +2 mg/dL/min →, -1 to +1 mg/dL/min ↘, -2 to -1 mg/dL/min ↓, more than -2 mg/dL/min	Same
Sensor Calibration	Factory Calibrated	Same
Sensor Warm-up Time	1 hour	Same
Restriction on Non-adjunctive Use	Not for use to make treatment decisions in the first 12 hours	Same
Sensor Glucose Reading Range	40-400 mg/dL	Same
General Device Characteristic Differences		
Intended Use Population	Persons with diabetes mellitus age 12 and up.	Persons with diabetes mellitus age 4 and up.
Display Device	Rapid-Acting Insulin Pen Cap (i.e., White Cap) for glucose value and trend arrow	FreeStyle Libre 2 Reader
Mobile App	Alerts and system events, graph with recent glucose history, list of recent glucose and insulin history	No mobile app
Sensor Wireless Communications Protocol	Near Field Communication (NFC): (13.56 MHz RFID) Bluetooth Low Energy (BLE) 4.2	Near Field Communication (NFC): (13.56 MHz RFID) Bluetooth Low Energy (BLE) 4.0
Method of Obtaining Sensor Glucose Values	NFC Scan with Rapid-Acting Pen Cap (White Cap)	NFC Scan with Reader
Real-time Low/High Glucose Alarms	Mandatory very-low glucose alarm at 55 mg/dL and an optional low glucose alarm at 70 mg/dL, both on the Mobile App. For low glucose alarms,	Configurable low- and high-glucose alarm on the Readers. For low and high glucose alarms, a user-initiated action is required to see glucose reading.

	users must scan sensor with the White Cap to see glucose reading. No high glucose alarm. For high sensor glucose readings, the White Cap will display the correction insulin dose based on the lookup table.	
Glucose History Graph Views	12, 24, and 48 hours.	8 and 24 hours. Summary of history can be viewed for 7, 14, 30, or 90 days.
Insulin Therapy Display	HCP-prescribed insulin doses and logged dosing event.	No insulin therapy display.

VI Standards/Guidance Documents Referenced:

- 21 CFR 862.1355 (integrated continuous glucose monitoring system (iCGM)) special controls
- FDA Guidance document *Applying Human Factors and Usability Engineering to Medical Dev*ices (February 3, 2016)
- FDA Guidance document *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* (May 11, 2005)
- FDA Guidance document *Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices* (September 6, 2017)
- ISO 10993-1 (5th Edition): 2018 - Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ISO 10993-5 (3rd Edition): 2009 – Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
- ANSI/AAMI ES60601-1: 2005/(R)2012 and A1: 2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2005, MOD)
- IEC 60601-1-2 (Ed. 4.0): 2014 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic Disturbances - Requirements and Tests
- IEC 60601-1-11 (Ed. 2.0): 2015 - Medical electrical equipment - Part 1-11: 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
- ANSI IEEE C63.27-2017 - American National Standard For Evaluation Of Wireless Coexistence

- ASTM D4332-14 Standard Practice For Conditioning Containers, Packages, Or Packaging Components For Testing
- ASTM D4169-16 Standard Practice For Performance Testing Of Shipping Containers And Systems
- ISO 14971 (2nd Edition): 2007 - Medical Devices – Application of risk management to medical devices
- ISO 15223-1 (3rd Edition): 2016 - Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements 2016
- IEC 62366-1 (1.0 Edition): 2015 - Medical devices – Part 1: Application of usability engineering to medical devices
- IEC 62304 (Edition 1.1): 2015 Consolidated Version - Medical device software - Software life cycle processes
- AAMI TIR57: 2016 - Principles for medical device security- Risk Management
- ANSI UL 2900-1 (1st Edition): 2017 - Standard for Software Cybersecurity Network-Connectable Products, Part 1: General Requirements
- ANSI IEEE C63.18-2014 –American National Standard Recommended Practice for an On-site, Ad Hoc Test Method for Estimating Electromagnetic Immunity of Medical Devices to Radiated Radio-Frequency (RF) Emissions from RF Transmitters

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

   Precision for the adult population (18 years and older) was previously established in K193371. Precision data was reanalyzed for pediatric study subjects 12-17 years old and presented in the table below.

Subject age group	Coefficient of Variation (%)	Paired Absolute Difference (mg/dL)	Paired Absolute Relative Difference (%)	Number of Paired Readings
Adults (18+)	5.7	12.4	8.1	26791
Pediatric (12-17 years)	6.0	13.2	8.4	7659

2. Linearity:

   See Section A(4), Assay Reportable Range below.

3. Analytical Specificity/Interference:

For this device, ascorbic acid (vitamin C) has been shown to interfere with system performance. Analytical Specificity/Interference was previously assessed in K193371.

Based on the results of the clinical evaluation and bench testing for ascorbic acid, the following statements have been placed in the device labeling:

- User Manual Warning: Taking ascorbic acid (vitamin C) supplements while wearing the Sensor may falsely raise Sensor glucose readings. You can take doses of ascorbic acid up to 500 mg per day and make treatment decisions with the Sensor. Taking more than 500 mg of ascorbic acid per day may affect the Sensor readings which could cause you to miss a severe low glucose event. Ascorbic acid can be found in supplements including multivitamins. Some supplements, including cold remedies such as Airborne® and Emergen-C®, may contain high doses of 1000 mg of ascorbic acid and should not be taken while using the Sensor. See your healthcare professional to understand how long ascorbic acid is active in your body.
- Bigfoot Unity Mobile App On-Screen Warning: Do not take high doses of vitamin C (more than 500 mg per day). This may falsely raise your Sensor readings. Supplements like Airborne or Emergen-C have high doses of vitamin C. Read labeling for all supplements to determine vitamin C content.

4. Assay Reportable Range:

   Assay Reportable Range was previously assessed in K193371. The reportable range for the Bigfoot Unity is 40 to 400 mg/dL.

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

   Shelf-life of the FreeStyle Libre 2 sensor was previously assessed in K193371. The FreeStyle Libre 2 sensor has a storage shelf-life of 9 months. Shelf-life was evaluated at 36° – 82° Fahrenheit within the humidity range of 10% - 90%.

6. Detection Limit:

   If a glucose measurement is less than 40 mg/dL, the result will be displayed by the system as '< 40 mg/dL'. If the glucose measurement exceeds 400 mg/dL, the result will be displayed as '>400 mg/dL'.

7. Assay Cut-Off:

   N/A

8. Accuracy (Instrument):

   N/A

9. Carry-Over:

   N/A

B Comparison Studies:

1. Method Comparison with Predicate Device:

   N/A. Accuracy is determined by comparing device values to an FDA cleared laboratory grade glucose measurement method and was previously assessed in K193371.

2. Matrix Comparison:

   N/A. Interstitial fluid is the only indicated matrix.

C Clinical Studies:

1. Clinical Sensitivity:

   N/A

2. Clinical Specificity:

   See Section A(3), Analytical Specificity/Interference, above.

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

   Two prospective clinical studies were conducted in the United States to support clearance of the predicate device in K193371. The pediatric study data was reanalyzed to align with the proposed intended user population of the Bigfoot Unity (12 years and older).

   In both studies, accuracy of the FreeStyle Libre 2 sensor was evaluated by comparing iCGM glucose values to an FDA-cleared laboratory grade comparator method (CM, using the YSI 2300). Glucose values were obtained from the iCGM and from the comparator at the same or similar time. The accuracy of iCGM glucose versus the comparator method was assessed by calculating the percentage of iCGM readings that were within 15%, 20%, and 40% for reference values ≥70 mg/dL, and within 15 mg/dL, 20 mg/dL, and 40 mg/dL for values < 70 mg/dL. For glucose values < 70 mg/dL, the difference in mg/dL between the CGM and comparator glucose values was calculated. For values ≥70 mg/dL, the relative difference (%) to the comparator value was calculated.

   Data from the two clinical studies are presented in the tables below.

Percent and Point Accuracy by iCGM Glucose Range (Adult)

iCGM Glucose Range (mg/dL)	No. Pair	Percent within 15 mg/dL (95% LCL*)	Percent within 40 mg/dL (95% LCL)	Percent within 15% (95% LCL)	Percent within 40% (95% LCL)	Mean Bias, mg/dL (95% UCL*)
<70	3530	89.0 (86.7)	99.4 (99.1)			-2.9 (-1.9)
70-180	7785			75.9 (73.1)	99.6 (99.4)	-5.8 (-4.1)
>180	7420			91.5 (89.4)	100.0 (99.9)	-6.5 (-4.1)

*95% LCL is the lower bound of the 95% confidence limit and 95% UCL is the upper bound of the 95% confidence limit

Percent and Point Accuracy by iCGM Glucose Range (Pediatric)

iCGM Glucose Range (mg/dL)	No. Pairs	Percent within 15 mg/dL (95% LCL)	Percent within 40 mg/dL (95% LCL)	Percent within 15% (95% LCL)	Percent within 40% (95% LCL)	Mean Bias, mg/dL (95% UCL)
<70	879	85.9 (80.5)	98.5 (97.2)			-5.4 (-3.0)
70-180	1963			76.2 (72.2)	99.1 (98.6)	-5.1 (-2.3)
>180	2226			89.1 (86.4)	99.7 (99.4)	-6.1 (-2.3)

Percent and Point Accuracy by Comparator Glucose Range (Adult)

CM Glucose Range (mg/dL)	No. Pair	Percent within 15 mg/dL (95% LCL)	Percent within 40 mg/dL (95% LCL)	Percent within 15% (95% LCL)	Percent within 40% (95% LCL)	Mean Bias, mg/dL (95% UCL)
<70	3468	95.3 (93.9)	100.0 (100.0)			1.5 (2.4)
70-180	7504			76.5 (73.8)	99.6 (99.4)	-4.8 (-3.5)
>180	7763			88.9 (86.3)	99.9 (99.8)	-8.7 (-6.3)

Percent and Point Accuracy by Comparator Glucose Range (Pediatric)

CM Glucose Range (mg/dL)	No. Pairs	Percent within 15 mg/dL (95% LCL)	Percent within 40 mg/dL (95% LCL)	Percent within 15% (95% LCL)	Percent within 40% (95% LCL)	Mean Bias, mg/dL (95% UCL)
<70	787	94.9 (91.1)	100.0 (100.0)			2.2 (3.6)
70-180	2001			74.2 (69.9)	98.8 (98.1)	-3.5 (-1.4)
>180	2298			87.9 (84.7)	99.8 (99.5)	-9.0 (-4.8)

Percent of iCGM values within 20% of Comparator Glucose Values

iCGM Glucose Range (mg/dL)	No. Pairs	No. Subject	Percent within 20% (95% LCL)
Adult (18 years and up)	18735	144	90.2 (88.7)
Pediatric (12-17 years)	5086	86	89.6 (86.6)

Percent 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 iCGM and laboratory comparator are presented in the tables below.

Accuracy to Comparator within iCGM Glucose Ranges (Adult; n=144)

CGM Glucose Level(mg/dL)	Number of CGM-Reference Pairs	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	518	85.9	93.8	99.4				-6.4	13.8
54-69	3012	89.5	94.2	99.1				-3.3	10.8
70-180	7785				76.5	86.6	99.2	-4.8	10.6
181-250	3037				89.1	95.0	99.9	-10.1	7.8
>250	4383				94.0	97.9	100.0	-6.3	6.1

Accuracy to Comparator within iCGM Glucose Ranges (Pediatric; n=86)

CGM Glucose Level (mg/dL)	Number of CGM-Reference Pairs	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	125	70.4	77.6	96.8				-10.9	17.8
54-69	772	86.5	90.4	96.9				-4.9	12.0
70-180	1963				76.9	86.6	98.5	-4.1	10.9
181-250	957				87.0	96.0	99.9	-11.7	8.1
>250	1269				93.5	98.1	99.7	-5.7	7.1

Accuracy to Comparator within Comparator Glucose Ranges (Adult; n=144)

CM Glucose Level (mg/dL)	Number of CGM-Reference Pairs	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	440	91.1	97.5	100.0				7.4	15.5
54-69	3028	94.7	98.6	100.0				1.5	10.2
70-180	7504				77.5	86.9	99.4	-4.8	10.4
181-250	2937				87.9	93.7	99.7	-8.0	8.0
>250	4826				90.9	95.9	99.7	-11.8	6.9

Accuracy to Comparator within Comparator Glucose Ranges (Pediatric; n=86)

CM Glucose Level (mg/dL)	Number of CGM-Reference Pairs	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	117	94.0	98.3	100.0				6.7	14.6
54-69	670	96.1	98.7	100.0				0.9	9.5
70-180	2001				73.3	83.3	97.7	-4.5	11.7

181-250	806				87.5	92.9	98.6	-6.0	8.3
>250	1492				91.1	98.1	99.9	-12.8	7.7

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, 351-400 and >400 mg/dL were evaluated against the comparator glucose ranges and percent of iCGM values within those ranges were reported.

Concurrence Analysis by iCGM Glucose Level (Adult; n=144)

CGM Glucose Level (mg/dL)	Comparator Glucose Level (mg/dL)											N
	<40	40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400	>400	
<40	20.0	20.0	40.0	20.0								5
40-60	0.4	52.9	43.3	3.3		0.1						1889
61-80		18.9	62.7	18.1	0.4	0.0						3090
81-120		0.2	11.0	70.1	17.8	0.8	0.1					3040
121-160			0.1	9.1	69.9	18.9	1.6	0.3	0.2			2407
161-200					10.6	60.6	26.9	1.6	0.3			1745
201-250						7.0	65.5	25.6	1.9	0.1		2181
251-300						0.1	8.4	66.9	22.7	1.8	0.1	2327
301-350							0.4	13.6	68.8	16.0	1.2	1522
351-400								0.6	27.5	63.3	8.6	534
>400									2.5	62.8	34.7	121

Concurrence Analysis by iCGM Glucose Level (Pediatric; n=86)

CGM Glucose Level (mg/dL)	Comparator Glucose Level (mg/dL)											N
	<40	40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400	>400	
<40		50.0	50.0									2
40-60	0.6	47.7	42.9	8.1	0.6							480
61-80		13.1	61.2	23.8	1.8							776
81-120		0.3	12.0	68.7	17.5	1.4	0.1					798
121-160				10.6	70.0	17.3	2.1					577
161-200				0.2	16.2	59.5	23.9	0.2				444
201-250						7.8	52.8	38.3	1.1			742
251-300							10.1	62.1	26.8	1.1		665
301-350							0.2	20.0	60.0	19.6	0.2	455
351-400						1.3		0.7	34.2	58.4	5.4	149
>400								6.7	6.7	16.7	70.0	30

Concurrence Analysis by Comparator Glucose Level (Adult; n=144)

CM Glucose Level (mg/dL)	CGM Glucose Level (mg/dL)											N
	<40	40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400	>400	
<40	12.5	87.5										8
40-60	0.1	62.9	36.6	0.4								1591
61-80	0.1	26.4	62.6	10.8	0.1							3093
81-120	0.0	2.1	18.8	71.1	7.3							2971
121-160			0.5	22.3	69.6	7.7						2418
161-200		0.1	0.1	1.5	26.9	62.5	9.0	0.1				1694
201-250				0.1	1.8	21.9	66.8	9.1	0.3			2139
251-300					0.3	1.2	23.7	66.0	8.8	0.1		2359
301-350					0.3	0.3	2.3	29.8	58.9	8.3	0.2	1777
351-400							0.3	6.1	34.7	48.1	10.8	703
>400								1.9	16.7	42.6	38.9	108

Concurrence Analysis by Comparator Glucose Level (Pediatric; n=86)

CM Glucose Level (mg/dL)	CGM Glucose Level (mg/dL)											N
	<40	40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400	>400	
<40		100										3
40-60	0.3	68.6	30.5	0.6								334
61-80	0.1	26.4	61.1	12.3								778
81-120		4.7	22.2	65.7	7.3	0.1						834
121-160		0.5	2.2	22.1	63.8	11.4						633
161-200				2.5	23.0	60.7	13.3			0.5		435
201-250				0.2	2.1	18.3	67.7	11.6	0.2			579
251-300						0.1	35.9	52.1	11.5	0.1	0.3	792
301-350							1.6	34.8	53.3	10.0	0.4	512
351-400								3.7	47.3	46.3	2.7	188
>400									3.3	26.7	70.0	30

Trend Accuracy

Trend accuracy describes the accuracy of the sensor during times of rapidly changing glucose and is characterized by slopes, such as from > 2mg/dL/min to <-2 mg/dL/min. Trend accuracy was assessed by the concurrence rate of the glucose rate of change from the iCGM and the corresponding comparator values for each iCGM-comparator measurement pair.

Concurrent Analysis by Glucose Rate of Change (Adult; n=144)

CGM (mg/dL/min)	Comparator (mg/dL/min)						N
	< -2	[-2, -1)	[-1, 0)	[0,1]	(1, 2]	>2	
< -2	34.4	44.9	18.3	2.2	0.3		323
-2 to -1	6.8	46.5	41.2	4.0	0.9	0.6	1090
-1 to 0	1.2	8.3	67.1	19.7	2.6	1.2	9389
0 to 1	0.9	3.4	26.0	46.9	15.5	7.3	5420
1 to 2	0.1	1.7	7.7	31.6	38.4	20.5	1151
> 2	0.1	0.2	3.1	14.6	32.9	49.0	881

Concurrent Analysis by Glucose Rate of Change (Pediatric; n=86)

CGM (mg/dL/min)	Comparator (mg/dL/min)						N
	< -2	[-2, -1)	[-1, 0)	[0,1]	(1, 2]	>2	
< -2	46.3	43.8	8.3	1.7			121
-2 to -1	12.7	51.2	30.8	4.4	0.3	0.6	338
-1 to 0	1.9	10.7	60.5	20.9	4.0	2.1	2084
0 to 1	0.9	5.0	25.8	43.0	15.3	9.9	1606
1 to 2	0.3	2.6	8.9	28.2	36.3	23.8	383
> 2		0.6	3.7	16.1	30.0	49.6	347

Agreement When iCGM Reads '<40 mg/dL' or '>400 mg/dL'

The System reports glucose concentrations between 40 and 400 mg/dL. When the System determines that the glucose level is below 40 mg/dL, it will report as '< 40 mg/dL' on the White Cap. When the System determines that glucose level is above 400 mg/dL, it will report as '> 400 mg/dL' on the White Cap.

The cumulative percentages of when the comparator values were less than certain glucose values (for '< 40 mg/dL') and when comparator values were more than certain glucose values (for '>400 mg/dL') are presented in the tables below

Concurrence Analysis with '<40 mg/dL' iCGM Reading (Adult; n=144)

CGM-Reference Pairs	Comparator (mg/dL)					N
	<50	<60	<70	<80	<90	
n	1	2	2	4	1	5
Cumulative %	20.0	40.0	40.0	80.0	20.0	

Concurrence Analysis with '<40 mg/dL' iCGM Reading (Pediatric; n=86)

CGM-Reference Pairs	Comparator (mg/dL)					N
	<50	<60	<70	<80	<90	
n	0	1	2	2	0	2
Cumulative %	0.0	50.0	100.0	100.0	0.0	

Concurrence Analysis with '>400 mg/dL' iCGM Reading (Adult; n=144)

CGM-Reference Pairs	Comparator (mg/dL)				N
	>350	>300	>250	≤250	
n	118	121	121	0	121
Cumulative %	97.5	100.0	100.0	0.0	

Concurrence Analysis with '>400 mg/dL' iCGM Reading (Pediatric; n=86)

CGM-Reference Pairs	Comparator (mg/dL)				N
	>350	>300	>250	≤250	
n	26	28	30	0	30
Cumulative %	86.7	93.3	100.0	0.0	

Alarm Performance

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

True Alarm Rate: Percentage of time the alarm issued, and blood glucose was below the alarm level within 15 minutes before or after the alarm.

False Alarm Rate: Percentage of time the alarm issued, and blood glucose was not below the alarm level within 15 minutes before or after the alarm.

Detection Rate: Percentage of time blood glucose was below the alarm level and the alarm issued within 15 minutes before or after the glucose event.

Missed Detection Rate: Percentage of time blood glucose was below the alarm level and the alarm didn't issue within 15 minutes before or after the glucose event.

Low Glucose Alert Performance (Adult; n=144)

Low Glucose Alert Level (mg/dL)	Alert Rate			Detection Rate		
	Number of Events (n)	True Alert Rate (%)	False Alert Rate (%)	Number of Events (n)	Correction Detection Rate (%)	Missed Detection Rate (%)
70	21504	86.0	14.0	3652	89.3	10.7

Low Glucose Alert Performance (Pediatric; n=86)

Low Glucose Alert Level (mg/dL)	Alert Rate			Detection Rate		
	Number of Events (n)	True Alert Rate (%)	False Alert Rate (%)	Number of Events (n)	Correction Detection Rate (%)	Missed Detection Rate (%)
70	1133	80.1	19.7	800	93.5	6.5

The Bigfoot Unity does not have high glucose alerts.

Sensor Stability

Sensor stability describes the performance of the sensor over the sensor lifetime. Sensors can be worn for up to 14 days. Performance was estimated by calculating the mean of the absolute relative differences between iCGM and comparator measurement and percentage of device readings within 15 mg/dL or 15% (15/15%), 20 mg/dL or 20% (20/20%) and 40 mg/dL or 40% (40/40%) of the comparator values during the beginning, early middle, late middle, and end of the wear period. These times were defined as follows:

- Beginning (Adult Days 1-3, Pediatric: Days 1-2)
- Early Middle (Adult: Days 7-8, Pediatric: Days 7-8),
- Late Middle (Adult: Days 9-12, Pediatric: Days 9-12), and
- End (Adult: Days 13-14, Pediatric: Days 13-14).

The mean absolute relative difference (MARD) and agreement rates with the comparator method were evaluated over 14-day life of the sensor.

Sensor Accuracy Relative to Comparator over the wear duration (Adult; n=144)

Wear Period	Number CGM-reference pairs	MARD (%)	Within ±15% / ±15 mg/dL	Within ±20% / ±20 mg/dL	Within ±40% / ±40 mg/dL
Beginning	6955	9.9	83.4	90.4	99.3
Early Middle	4522	8.5	87.7	94.5	99.8
Late Middle	3503	8.8	86.8	93.4	99.7
End	3755	9.1	86.4	92.9	100.0

Sensor Accuracy Relative to Comparator over the wear duration (Pediatric; n=86)

Wear Period	Number CGM-reference pairs	MARD (%)	Within ±15% / ±15 mg/dL	Within ±20% / ±20 mg/dL	Within ±40% / ±40 mg/dL
Beginning	1403	10.9	79.3	88.0	98.2
Early Middle	1307	8.0	90.0	94.3	98.2
Late Middle	1068	9.8	84.1	92.6	99.8
End	1308	10.2	83.9	91.8	99.4

Sensor Life

The Sensor can be worn for up to 14 days. To estimate how long a Sensor will work over the wear duration, 146 Sensors were evaluated in the Adult study and 87 Sensors were evaluated in the Pediatric study to determine how many days of readings each Sensor provided. Subjects did not wash the insertion site with soap and water before applying the Sensors and wore two Sensors simultaneously. Of the 146 Sensors in the Adult study, 71.1% lasted until the final day of use. 6 Sensors (4.1%) had "early sensor shut-off" where the Sensor algorithm detected that the Sensors did not function as intended and presented the user with a Replace Sensor message. In the Pediatric study, 80.3% of the Sensors lasted until the final day of use. 2 Sensors (2.3%) had "early sensor shut-off" where the Sensor algorithm detected that the Sensors did not function as intended and presented the user with a Replace Sensor message.

Sensor Survival Rate Over Wear Duration (Adult; n=146)

Day of Wear	Number of Sensors	Survival Rate (%)
1	145	99.3
2	142	97.3
3	140	95.9
4	137	93.8
5	134	91.8
6	133	91.1
7	132	90.4
8	127	87.0
9	123	84.9
10	119	82.2
11	112	77.3
12	111	76.6
13	104	71.8
14	100	71.1

Sensor Survival Rate Over Wear Duration (Pediatric; n=87*)

Day of Wear	Number of Sensors	Survival Rate (%)
1	85	97.7
2	84	96.6
3	83	95.4
4	82	94.3
5	82	94.3
6	82	94.3
7	82	94.3
8	82	94.3
9	79	90.8
10	77	88.5
11	77	88.5
12	76	87.4
13	74	85.1
14	67	80.3

* Performance tables provided are based on the paired data against the comparator reference from 86 subjects. For one of the subjects, the sensor did not survive through their in-clinic session, resulting in no pair sensor-comparator method reference. However, that subject's sensor is included in calculating the sensor survival, resulting in 87 sensors.

A third clinical study was also conducted to further evaluate wear duration in subjects who first washed the insertion site with a plain soap and water, according to the full instructions in the labeling and wore only a single Sensor. Of the 39 Sensors evaluated in this study, 97% lasted until the final day of use.

Glucose Reading Availability

The System is designed to show a Sensor glucose reading after each scan that is performed throughout the wear period after the start-up time. As such, the capture rate characterizes the reliability of the communication between components of the system.

Glucose Reading Capture Rate Over Wear Duration (Adult; n=146)

Day of Wear	Number of Sensors	Survival Rate (%)
1	146	98.3
2	145	98.1
3	143	98.3
4	140	98.3
5	138	98.4
6	135	98.3
7	134	98.4
8	131	98.4
9	128	98.4
10	123	98.4
11	120	98.4
12	113	98.5
13	112	98.5
14	104	98.6

Glucose Reading Capture Rate Over Wear Duration (Pediatric; n=87)

Day of Wear	Number of Sensors	Survival Rate (%)
1	87	95.4
2	85	95.2
3	84	95.6
4	82	95.7
5	83	95.9
6	82	96.1
7	83	96.5
8	82	96.8
9	81	96.9
10	78	96.9
11	78	96.9
12	76	97.1

13	75	97.1
14	74	97.2

D Clinical Cut-Off:

N/A

E Expected Values/Reference Range:

N/A

F Other Supportive Instrument Performance Characteristics Data:

Human Factors
Human factors and usability testing of the System was conducted in accordance with the FDA Guidance, *Applying Human Factors and Usability Engineering to Medical Devices (February 3, 2016)* to evaluate the safe and effective use of the Bigfoot Unity for the intended users, uses, and use environment.

Validation data demonstrated that use-related risk was brought to an acceptable level and that no serious use errors or problems associated with high levels of residual risk remain.

Software Verification and Validation
Software verification and validation testing was conducted to confirm that the software used in the Bigfoot Unity performed in accordance with established specifications and FDA Guidance document "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005)".*

Biocompatibility
Biocompatibility testing in accordance with ISO10993-1 and FDA Guidance *"Use of International Standard ISO 10993-1, Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process (June 16, 2016)"* was performed on the Black Cap and the White Cap of the Bigfoot Unity. Biological evaluation included cytotoxicity, irritation, and sensitization testing. All biocompatibility testing met the acceptance criteria.

Sterilization
The only sterile component of the Bigfoot Unity is the FreeStyle Libre 2 sensor. The sterility of the sensor was established in K193371.

Pen Cap Cleaning
The pen caps are intended to be used over a 2-year period by a single patient and cleaned as needed using water or isopropyl alcohol wipes to clean the outside or a six-inch-long cotton swab to clean the inner cavity of the cap. The cleaning regimen provided in the use guide is intended to maintain the pen cap's functionality but is not intended to be a validated disinfection process.

Shelf Life and Stability
Shelf-life of the FreeStyle Libre 2 sensor was previously assessed in K193371.
Accelerated aging/storage life testing was conducted which supports a 2-year shelf life of the pen cap materials.

Packaging Integrity/Shipping Integrity
Packing and shipping integrity testing evaluated the First Time Experience (FTE) Kit packaging in accordance with ASTM D4332-14 and ASTM D4169-16 guidelines. All tested units passed the testing requirements of all distribution tests.

Electromagnetic Compatibility
Electromagnetic compatibility (EMC) testing was performed for the Bigfoot Unity to verify that the system demonstrated compliance with requirements of IEC 60601-1-2:2014 (ed. 4) and Federal Communication Commission Regulations Part 15, Subpart B. In the context of electromagnetic emissions and immunity, testing and the accompanying documents (or labeling) support the safe use of the system in the home healthcare environment. Bigfoot performed testing to AAMI TIR69:2017: Risk Management of Radio-Frequency Wireless Coexistence For Medical Devices And Systems and ANSI/IEEE C63.27:2017: American National Standard for Evaluation of Wireless Coexistence and demonstrated wireless coexistence for their device.

Electrical Safety
The basic safety and essential performance of the Bigfoot Unity was evaluated in accordance with ANSI/AAMI ES6060-1: 2005/(R)2012 and A1: 2012, C1:2009/(R)2012 and A2:2010/(R)2012, as well as IEC 60601-1-11 (ed. 2.0): 2015 and demonstrated compliance to the requirements.

Blood Glucose Meter Functionality
The Bigfoot Unity is compatible with the Bigfoot Meter, a wirelessly connected blood glucose meter previously cleared under K152365 and privately labeled for Bigfoot. The Bigfoot Meter is compatible with Bigfoot Test Strips and AgaMatrix Control Solutions.

Interoperability
The Bigfoot Unity communicates with the FreeStyle Libre 2 sensor by utilizing the Abbott Diabetes Care (ADC) software library. Bigfoot's verification and validation activities occurred at a product level in addition to software-specific testing and demonstrate that the integration with the ADC Sensor and library has been successful.

Cybersecurity
The sponsor has provided cybersecurity risk management documentation for the Bigfoot Unity that includes the cybersecurity mitigations of the Abbott Diabetes Care FreeStyle Libre 2 CGM. Bigfoot has provided their analysis of threats to confidentiality, integrity, and availability for data and software in the System. Bigfoot identified vulnerabilities and completed a risk assessment for the impact to confidentiality, integrity, and availability. Risk mitigation controls have been implemented and verified.

In addition, Bigfoot has controls and processes in place to ensure continued support for keeping the device secure and to ensure that the device firmware, software and components are malware free. Bigfoot has provided a Software Bill of Materials (SBOM), which captures relevant details for each of the software components utilized in the system, including a review of the National

Vulnerability Database (NVD) to assess if each software component has any open vulnerabilities. Additional controls are in place in manufacturing through distribution to ensure that the medical device firmware and software remain malware free from point of origin to the hands of the end user.

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.