



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

I Background Information:

A 510(k) Number

K222280

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 - Piston Syringe	General Hospital

II Submission/Device Overview:

A Purpose for Submission:

Modification to an existing device to add the Android mobile app as an alternate primary display and to add the silence all alarms feature

B Measurand:

Glucose in interstitial fluid

C Type of Test:

Quantitative, amperometric assay via 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 Contraindications

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

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 Sensor has not been evaluated

D Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

Taking ascorbic acid (vitamin C) supplements while wearing the Sensor may falsely raise Sensor glucose readings. Taking more than 500 mg of ascorbic acid per day may affect the Sensor readings which could result in a severe low glucose event.

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

Do not use the 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 implanted medical devices, such as pacemakers.

The System does not support insulin doses in half-unit increments. Patients that require half doses 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 help 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 exceed 82°F (e.g., an un-airconditioned home in the summer), you should refrigerate 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 inaccurate glucose readings.

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

If you use an Android phone, do not lower the notification vibration. If you use an Android phone, do not lower the notification vibration intensity to the lowest level in your phone's Vibration Intensity menu. At the lowest level, you may not detect vibrations with your alerts, including the Very Low Glucose Alert.

If you use an iPhone, do not turn off vibration in the iOS Sound & Haptics or Accessibility menus. If you turn off any vibration setting, you will not get any vibrations with your alerts, including the Very Low Glucose Alert.

E Special Instrument Requirements:

Not Applicable

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 healthcare provider (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 mg/dL and an optional low-glucose alarm at 70 mg/dL. The alarms are able to be silenced for up to 4 hours through the mobile app, but alarms will still be pushed as notifications and vibrate as they occur. 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:

Not Applicable

3. Specimen Sampling and Handling:

Not Applicable

4. Calibration:

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

5. Quality Control:

Not Applicable

V Substantial Equivalence Information:

A Predicate Device Name(s):

Bigfoot Unity Diabetes Management System

B Predicate 510(k) Number(s):

K202145

C Comparison with Predicate(s):

Device & Predicate Device(s):	<u>K222280</u>	<u>K202145</u>
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	<p>↑, more than +2 mg/dL/min</p> <p>↗, +1 and +2 mg/dL/min</p> <p>→, -1 to +1 mg/dL/min</p> <p>↘, -2 to -1 mg/dL/min</p> <p>↓, more than -2 mg/dL/min</p>	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		
Mobile Phone Operating System	Android and Apple iOS	Apple iOS
Mandatory Alerts	<p>Able to silence all alerts and alarms (includes very low glucose alarm <55 mg/dL) for up to 4 hours while maintaining vibration annunciation.</p> <p>User can manually turn off specific alerts and alarms in the mobile application except for very low glucose alarm when not in silence mode.</p>	<p>Mandatory low glucose alarm (<55 mg/dL) cannot be silenced.</p> <p>Users cannot turn off specific alerts and alarms.</p>

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 Devices* (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 was established in K202145 and there are no changes in this submission.

2. Linearity:

Linearity was established in K202145 and there are no changes in this submission.

3. Analytical Specificity/Interference:

Analytical specificity and interference parameters were established in K202145 and there are no changes in this submission.

4. Assay Reportable Range:

Assay reportable range was established in K202145 and there are no changes in this submission.

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

Same as in K193371.

6. Detection Limit:

Unchanged since K193371.

7. Assay Cut-Off:

Not Applicable

8. Accuracy (Instrument):

Not Applicable

9. Carry-Over:

Not Applicable

B Comparison Studies:

1. Method Comparison with Predicate Device:

Not Applicable. Accuracy is determined by comparing device values to an FDA cleared laboratory grade glucose measurement method and was previously assessed in K193371.

2. Matrix Comparison:

Not Applicable. Interstitial fluid is the only indicated matrix.

C Clinical Studies:

1. Clinical Sensitivity:

Not Applicable

2. Clinical Specificity:

Not Applicable

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

Clinical performance of the device was established in K193371 and K202145.

D Clinical Cut-Off:

Not Applicable

E Expected Values/Reference Range:

Not Applicable

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 followed FDA Guidance document “*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005)*.”

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.

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.