March 1, 2023

Bigfoot Biomedical, Inc.
Kate Lee
SVP, Regulatory and Quality
1820 McCarthy Blvd
Milpitas, CA 95035

Re: K222280
Trade/Device Name: Bigfoot Unity® Diabetes Management System
Regulation Number: 21 CFR 862.1355
Regulation Name: Integrated Continuous Glucose Monitoring System
Regulatory Class: Class II
Product Code: QLG, QOG
Dated: December 7, 2022
Received: December 7, 2022

Dear Kate Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR

803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Paula Caposino -S
Digitally signed by Paula Caposino -S
Date: 2023.03.01 13:19:34 -05'00'

Paula Caposino, Ph.D.
Acting Deputy Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below

510(k) Number *(if known)*
K222280

Device Name

Bigfoot Unity® Diabetes Management System

Indications for Use *(Describe)*

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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) SUMMARY

Bigfoot Unity® Diabetes Management System

I. Submitter:

Address:	Bigfoot Biomedical, Inc. 1820 McCarthy Blvd Milpitas, CA 95035
Phone:	(408) 716-5600
Contact:	Kate Lee
Date Prepared:	February 14, 2023

II. Device: K222880

Name of Device:	Bigfoot Unity® Diabetes Management System
Common Name:	Integrated Continuous Glucose Monitor
Classification Name:	Integrated Continuous Glucose Monitoring System, Factory Calibrated, Not For Use With Automated Insulin Delivery Systems
Regulatory Class:	Class II (21 CFR §862.1355, 21CFR § 880.5860)
Product Code:	QLG, QOG

III. Predicate Device:

Bigfoot Unity® Diabetes Management System – K202145

IV. Device Description:

The Bigfoot Unity Diabetes Management System ('Bigfoot Unity System') integrates continuous glucose monitoring with insulin dose recommendations to support people with diabetes mellitus who use disposable insulin pens for self-injection of insulin. The system consists of the Abbott Diabetes Care, Inc. FreeStyle Libre 2 Flash Glucose Monitoring System ("FreeStyle Libre 2") integrated continuous glucose monitor (iCGM) sensor, 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.

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 rapid-acting pen cap also displays correction and meal insulin doses based upon settings prescribed by the user's healthcare provider and the available glucose data. The long-acting pen 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 and current exercise status, users determine the doses to take. Users manually select an insulin dose and administer it using the pens according to the insulin manufacturers' instructions. In addition to dose information, both pen caps track the time of insulin doses.

The mobile app provides fixed and configurable system alerts based upon data generated by the FreeStyle Libre 2 sensor. It also enables entry of the healthcare provider prescribed insulin dosingregimen as well as provides system alerts and historical information. In addition, the mobile app manages the secure wireless communication between the system components and enables the transfer of the system data to the cloud.

V. Intended Use / Indications 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.

VI. Technological Characteristics

The Bigfoot Unity System has the same intended uses and similar indications, technological characteristics, and principles of operation compared to the predicate device. Bigfoot Unity incorporates the FreeStyle Libre 2 sensor, using the same technology to measure interstitial glucose and provide real-time glucose data to the user. The minor technological differences between the Bigfoot Unity System and its predicate device primarily relate to expansion to Android OS compatible smartphones. These technical differences do not impact the availability of accurate data to support the user in making appropriate dosing decisions. Thus, they do not raise new questions ofsafety or effectiveness. Performance data additionally demonstrates that the Bigfoot Unity System is as safe and effective as its predicate device.

VII. Performance Data

Bench test results support the performance characteristics of the Bigfoot Unity System and show equivalence to the currently marketed predicate device. In all instances, the Bigfoot Unity System functioned as intended and the results of the testing met the acceptance criteria.

- **Software Verification and Validation:** Software verification and validation testing was conducted to confirm that the software used in the Bigfoot Unity System performed in accordance with established specifications, in accordance with FDA's *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* (May 11, 2005) and FDA's Draft Guidance, *Content of Premarket Submissions for Device Software Functions*. Verification activities included unit, component, system integration, and system level testing which verified functionality of the device against established software requirements. Results of the software executed protocols for the Unity System met the acceptance criteria and therefore support that the Bigfoot Unity software is acceptable for its intended use.

- **Human Factors:** Human factors and usability testing of the Bigfoot Unity System was conducted to determine whether the user interface design and labeling enabled safe and effective use of the device by the intended user groups. Human factors testing was conducted in accordance with FDA Guidance, *Applying Human Factors and Usability Engineering to Medical Devices* (2016) and ANSI/AAMI/IEC 62366: *Medical devices - Application of Usability Engineering to Medical Devices.*

- **Electromagnetic Compatibility and Electrical Safety:** The Bigfoot Unity System has been tested and shown to comply with the electrical safety and electromagnetic compatibility requirements in IEC 60601-1:2005*, Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance,* IEC/EN 60601-1-2:2014 and IEC CISPR 11. Additionally, the Bigfoot Unity System complies with IEC 60601-1-11:2015, *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*. Wireless coexistence and EMC testing were performed to confirm that the Bigfoot Unity System remains functional and performs within acceptable limits while in the presence of common radiating electronic devices in accordance with applicable standards as well as FDA's guidance, *Radio Frequency Wireless Technology in Medical Devices*. The Bigfoot Unity System demonstrated successful coexistence testing in the presence of common RF interfering devices (2.4 GHz frequency band) that are likely to be encountered by users in a home environment. The Bigfoot Unity System also successfully demonstrated compliance with airworthiness requirements per the Federal Aviation Administration (FAA) Advisory Circular *RTCA/DO-160.*

- **Cybersecurity:** Cybersecurity risk management was performed including analysis of confidentiality, integrity, and availability for data, information and software related to the Bigfoot Unity System. Appropriate risk mitigation controls have been implemented and tested.

The following performance characteristics were established for the predicate Bigfoot Unity System in K202145 and are not impacted by the modifications leading to the subject device.

- Interoperability
- Environmental Testing (operating parameters, shock resistance, storage conditions, etc.)
- Biocompatibility
- Analytical and Clinical Performance

VIII. Conclusion

The Bigfoot Unity System has the same intended use and clinical application as its predicate (the prior version of the device). There are no differences in technological characteristics that raise questions of safety or effectiveness. The Bigfoot Unity System provides significant benefits to users (ease of use/accessto insulin dose recommendations based on glucose information where the user manually controls actions for therapy decisions) that outweigh any potential risks associated with manual management of care. Bench testing along with human factors testing demonstrated that the subject Bigfoot Unity System provides accurate and reliable dose recommendation based on current standard of care from a healthcare provider. Accordingly, and based on the submitted data, the subject device has been shown to be substantially equivalent to its predicate.