K130621

510(k) Summary
(Per 21 CFR 807.92)

JUL 3 0 2013

1. Submitter Information

Company Name	BroadMaster Biotech Corporation
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Date Prepared	2013/1/18

2. Device Name

Proprietary Name	BroadMaster HealthCare System
Common Name	BroadMaster HealthCare System
Classification Number	System, Test, Blood Glucose, Over the Counter Calculator/data processing module, for clinical use
Classification Panel	75, Clinical Chemistry
Product Code	NBW, JQP
Regulation Number	21 CFR 862.1345 Glucose Test System 21 CFR 862.2100 Calculator/data processing module for clinical use.

3. Predicate Device

Proprietary Name	Clever Check Health System Software
Common Name	Clever Check Health System Software
Manufacturer	TaiDoc Technology Corporation
510(k) Number	k070941

4. Device Description

The BroadMaster HealthCare System is a software designed to collect user glucose raw data, analyze results with easy-to-read trend graphs and save glucose raw data to .csv file for report. This system is very easy and friendly to use, even if user has a little computer experience. The BroadMaster HealthCare System Software works with its own behind-the-scene database to store glucose raw data from the glucose device. Glucose raw data downloaded to the software system are

stored under the user profile that was selected before the download. In short, the BroadMaster HealthCare System will help user to store the blood glucose device readings, analyze results with easy-to-read trend graphs, and save glucose raw data to .csv file for report.

5. Intended Use

The BroadMaster HealthCare System is a software accessory compatible with legally marketed BroadMaster Biotech glucose meters, such as the Glucose Shepherd Blood Glucose Monitoring System and ADVOCATE® Redi-Code+ BMB-EA001S Blood Glucose Monitoring System and is intended for use in the home setting by people with diabetes. It is intended to aid in the review, analysis, and evaluation of patient data to support diabetes management. The BroadMaster HealthCare System receives via USB, stores, and uses patient data for display and reporting, sets meter date, time and alarm. The software is designed for multiple users use and only compatible with personal computer. It's not compatible with other devices such as PDAs or smartphones.

6. Comparison to Predicate Device

Table 1 Software function Comparison

Items	BroadMaster HealthCare System Software	Clever Check Health System Software
510(k) number	k130621	k070941
Personal Information	V	V
Current User	V	V
New User	V	V
Delete User	V	V
Download Glucose Raw Data	V	V
Show Glucose Raw Data	V	V
Export .csv file	V	V
Trend Graph	V	V
Print Trend Graph	V	V
Print Glucose Raw Data	V	V
PC Reminder	V	V
Set Device Time	V	V
Set Device Alarm Time	V	V
Delete Device Memory		V

Instrument Settings		V
Software Settings		V
Help button		V
Maximum screen button	V	
Minimize screen button	V	V
Close button	V	V

Table 2 Similarities and Differences

Similarities		
Item	Device	Predicate
Intended Use	Same intended use	Same intended use
Data Use	Data transferred from the device cannot be changed or modified.	Same
Differences		
Meter Compatibility	For use with BroadMaster Biotech Corp. meters	For use with TaiDoc meters
Software function	See Table 1	See Table 1

7. Performance Studies

The performance of the BroadMaster HealthCare System Software was studied in the laboratory settings. The studies have demonstrated that this system meets the performance requirements of its intended use.

8. User Studies

The user studies of the BroadMaster HealthCare System Software indicate that BroadMaster Healthcare System Software is not difficult to be operated by lay-users.

9. Conclusion

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 30, 2013

BroadMaster Biotech Corporation
C/O Roger Lai
7F, No. 168-1, No.168-2, Liancheng Rd., Zhonghe Dist.
New Taipei City 23553, Taiwan (R.O.C.)

Re: K130621
Trade/Device Name: BroadMaster HealthCare system
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, JQP
Dated: June 04, 2013
Received: June 28, 2013

Dear Mr. Lai:

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. 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for

the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias, Ph.D.

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): k130621

Device Name: The BroadMaster HealthCare System

Indications for Use:

The BroadMaster HealthCare System is a software accessory compatible with legally marketed BroadMaster Biotech glucose meters, such as the Glucose Shepherd Blood Glucose Monitoring System and ADVOCATE® Redi-Code' BMB-EA001S Blood Glucose Monitoring System and is intended for use in the home setting by people with diabetes. It is intended to aid in the review, analysis, and evaluation of patient data to support diabetes management. The BroadMaster HealthCare System receives via USB, stores, and uses patient data for display and reporting, sets meter date, time and alarm. The software is designed for multiple users use and only compatible with personal computer. It's not compatible with other devices such as PDAs or smartphones.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Katherine Serrano -S

Division Sign-Off

Office of In Vitro Diagnostics and Radiological Health

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