

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION  
DECISION SUMMARY  
INSTRUMENT ONLY TEMPLATE**

**A. 510(k) Number:**

k130621

**B. Purpose for Submission:**

New Diabetes Data Manager for use with the Glucose Shepherd Blood Glucose Monitoring System (k102316) and ADVOCATE Redi-Code+ BMB-EA001S Blood Glucose Monitoring System (k120183)

**C. Manufacturer and Instrument Name:**

BroadMaster Biotech Corp.

BroadMaster HealthCare System

**D. Type of Test or Tests Performed:**

Diabetes data management system

**E. System Descriptions:**

1. Device Description:

The BroadMaster HealthCare System, a PC-based software system, is an optional accessory to the Glucose Shepherd Blood Glucose Monitoring System and ADVOCATE Redi-Code+ BMB-EA001S Blood Glucose Monitoring System that aids in diabetes care and management. The BroadMaster HealthCare System receives test results from the indicated BroadMaster blood glucose meters via USB cable, and stores these results in a local database on the user's PC.

2. Principles of Operation:

The BroadMaster HealthCare System intakes user raw glucose data generated on the Glucose Shepherd Blood Glucose Monitoring System (k102316) and ADVOCATE Redi-Code+ BMB-EA001S Blood Glucose Monitoring System (k120183), allows analysis of results with trend graphs, and save glucose raw data for export. The BroadMaster HealthCare System uses a database to store glucose raw data downloaded via USB from the indicated BroadMaster glucose meters. Glucose raw data downloaded to the software system are stored under distinct user profiles. The software also allows the setting of the meter's time.

3. Modes of Operation:

Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device? Yes X or No \_\_\_\_.

Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission: Yes \_or No X.

4. Specimen Identification:

Specimen identification is based on time and date of testing

5. Specimen Sampling and Handling:

Data transmission from glucose meters using capillary whole blood samples.

6. Calibration:

Glucose meter specific. See statement below under section J.

7. Quality Control:

Glucose meter specific. See statement below under section J.

8. Software:

FDA has reviewed applicant's Hazard Analysis and Software Development processes for this line of product types:

Yes X or No \_\_\_\_\_

**F. Regulatory Information:**

<b>Product Code</b>	<b>Classification</b>	<b>Regulation Section</b>	<b>Panel</b>
NBW - Glucose test system, Over-the-Counter	Class II	21 CFR § 862.1345	Clinical Chemistry (75)
JQP – Calculator/data processing module, for clinical use	Class I	21 CFR § 862.2100	Clinical Chemistry (75)

**G. Intended Use:**

1. Indication(s) 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.

2. Special Conditions for Use Statement(s):

Over-the-counter use

**H. Substantial Equivalence Information:**

1. Predicate Device Name(s) and 510(k) numbers:

Clever Check Health System Software, k070941

2. Comparison with Predicate Device:

Similarities and Differences		
Item	Candidate Device <b>BroadMaster HealthCare System</b>	Predicate Device (k070941)
Intended Use	Same	Optional accessory to cleared glucose meters and is intended to aid in the review, analysis, and evaluation of patient data to support diabetes management.
Over-the-Counter	Same	Yes
Connectivity to Meter	USB	RS232

System Requirements	IBM® and Intel®-compatible PC; 1G MHz or higher Pentium® compatible processor 256 MB RAM; 600 MB of available hard drive space CD-ROM drive; keyboard and mouse or compatible pointing device; available USB port Minimum display resolution of 1024 x 768	Personal computer with 400 megahertz (MHz) or higher processor clock speed recommended; the software does not run on Apple computers. Random access memory (RAM) of 64 megabytes (MB) or more recommended. Available hard disk space of 30 MB for running the program. Monitor with 1024 x 768 or higher resolution.
Operating System	Windows XP, Vista (32- and 64-bit), 7 (32- and 64-bit)	Windows 98 SE, 2000, NT, ME, XP
Compatible Blood Glucose meters	Glucose Shepherd Blood Glucose Monitoring System (k102316) and ADVOCATE Redi-Code+ BMB-EA001S Blood Glucose Monitoring System (k120183)	TaiDoc glucose and glucose/blood pressure monitors (k061181, k062235, k063212, k070239, k070472, k062800, k070641, k051703)
Graphic Data Displays	Same	Yes
Editing of Patient Data	Same	No
Database location	Same	Local computer

**I. Special Control/Guidance Document Referenced (if applicable):**

1. US FDA guidance document, General Principles of Software Validation
2. IEC 601-1-4, Safety Requirements for Programmable Electronic Medical Systems
3. IEC 60601-1-4, Medical electrical equipment- Part 1-4: General requirements for safety
4. IEC 62304, Medical device software- Software life cycle processes
5. ISO 13485:2009, Medical devices- Quality management systems- Requirements for regulatory purposes
6. Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf
7. Software Use in Medical Devices", Sep. 9, 1999, CD

**J. Performance Characteristics:**

1. Analytical Performance:

The performance characteristics listed below as applicable, were presented in the specific glucose meter clearances under k102316 and k120183.

*a. Accuracy:*

See above statement under section J.1.

*b. Precision/Reproducibility:*

See above statement under section J.1.

*c. Linearity:*

See above statement under section J.1.

*d. Carryover:*

See above statement under section J.1.

*e. Interfering Substances:*

See above statement under section J.1.

2. Other Supportive Instrument Performance Data Not Covered Above:

A. Bench testing was conducted during design verification activities. Data was uploaded from compatible meters to the BroadMaster HealthCare System via USB cable on Windows based systems. Verification was performed on the following Operating systems:

Windows XP  
Windows Vista (32- and 64-bit)  
Windows 7 (32- and 64-bit)

Meter memory capacity and data rollover was performed on data from the Glucose Shepherd Blood Glucose meter and ADVOCATE Redi-Code+ BMB-EA001S Blood Glucose meter connected simultaneously to test meter memory rollover and data transmission. BroadMaster HealthCare System was verified to meet data upload accuracy (100%) and data management requirements.

B. Human Factors Study

36 subjects with typical computer experience and ages (age range 48 to 88 years old) were enrolled in the Human Factors study conducted for the BroadMaster HealthCare System. Participants were accessed on: installation of the software on their test computer syncing the meter date and time, data transmission, viewing data, generating and exporting reports. The data in participant created reports

matched the stored meter data in 100% of cases.

The ease-of-use study consisted of 36 lay-users with varying demographics (age, sex, and education level) were included in a usability study for installing, uploading data from glucose meters, and using features of the software. The participants were provided the user manual and no further instruction. Following the study the participants also completed a questionnaire in response to whether the data transmission feature is easy to use.

Study Feedback: The proportions of neutral-or-better responses (ranked 1-5) for all 14 items on the Survey Questionnaire for Usability meet the acceptance criterion of average response rate of  $>3$  (average 3.86).

- B. Software documentation was reviewed and demonstrated that the device was developed under appropriate software lifecycle processes. The following documentation related to the software was reviewed and found to be acceptable: level of concern, software description, device hazard analysis, software requirements specifications, software design specification, software development environment description, and verification and validation testing.
- C. The BroadMaster HealthCare System User's Guide Readability Assessment was at a 6.9 grade level using the Flesch-Kincaid readability assessment.

**K. Proposed Labeling:**

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

**L. Conclusion:**

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