

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

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

k102678

**B. Purpose for Submission:**

A new 510(k) for a diabetes management software accessory to a cleared blood glucose meter (k093262). The meter was modified in this submission to add the USB and address infection control requirements which included a change in the name of the meters.

**C. Manufacturer and Instrument Name:**

Andon Medical Co., Ltd.; Andon Health Care Management System Software, AG-608 Single and AG-608 Multi Blood Glucose Monitoring Systems

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

Diabetes data management system

**E. System Descriptions:**

1. Device Description:

Andon Health Care Management System Software is an optional software accessory for use with the Andon blood glucose meters with data management capacities. The system allows the user to download blood glucose results from their glucose meter to their computer and display the results as in tabular format or graphically to analyze blood glucose trends. The software does not recommend any medical treatment or dosing recommendations.

A PC link function was added to the cleared AG-608 meter (k093262). This link includes an IC which operates as a bridge between the USB port and a standard RS232 Serial port is integrated in the meter. The link allows for the interface with a PC for uploading of blood glucose measurements stored in the meter memory. A USB cable is used to connect a PC and the meter.

In this submission infection control validation studies were performed to validate the use of the AG-608 for use as a single-patient use system (AG-608 Single Blood Glucose Monitoring System) and as a multiple-patient use system (AG-608 Multi Blood Glucose Monitoring System). These systems are used with the previously cleared (k093262) test strips AGS-1000 Single and AGS-1000 Multi test strips. The names of the test strips were changed in k093755 to address the infection control requirements.

2. Principles of Operation:

The operating system requirements for the Andon Health Care Management System Software are: Windows XP, Windows Vista or Windows 7.

System requirements: 1.2 GHz; 256 MB RAM; 100 MB minimum free disk space; USB port and USB cable; graphic resolution minimum of 1024x768.

3. Modes of Operation:

Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

Yes  or No .

Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission:

Yes  or No .

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  or No .

**F. Regulatory Information:**

1. Regulation section:

21 CFR § 862.1345 Glucose Test System

21 CFR § 862.2100 Calculator/Data Processing Module for Clinical Use

2. Classification:

Class II, I (respectively)

3. Product code:

NBW, Blood Glucose Test System, Over-the-Counter  
JQP, Calculator/Data Processing Module for Clinical Use

4. Panel:

75 (Clinical Chemistry)

**G. Intended Use:**

1. Indication(s) for Use:

**Andon Health Care Management System Software** is an optional software accessory for use with the Andon blood glucose meters with data management capacities. When used with one of these meters, Andon Health Care Management System Software transfers data from the device's memory into a computer for enhanced data management. Andon Health Care Management System Software is intended for use in home and clinical settings via the internet to assist people with diabetes and their healthcare professionals in uploading, storing, analyzing, and communicating about historical blood glucose test results and other biological statistics to support diabetes management. Andon Health Care Management System Software is not intended to provide treatment decisions or to be used as a substitute for professional healthcare judgment. All patient medical diagnoses and treatment are to be performed under the supervision and oversight of an appropriate healthcare professional.

**The AG-608 Single Blood Glucose Monitoring System** is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips. The AG-608 Single Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

The AG-608 Single Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The AG-608 Single Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes, nor for neonatal use.

The AGS-1000 Single Blood Glucose Test Strips are for use with the AG-608 Single Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood sample.

**The AG-608 Multi Blood Glucose Monitoring System** is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips. The AG-608 MULTI Blood Glucose Monitoring System is intended to be used by healthcare professionals for multiple patients in a professional healthcare setting as an aid in monitoring the effectiveness of diabetes control.

The AG-608 MULTI Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes, nor for neonatal use. The AGS-1000 MULTI Blood Glucose Test Strips are for use with the AG-608 MULTI Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood sample.

This system should only be used with single-use, auto-disabling lancing devices.

2. Special Conditions for Use Statement(s):  
None

**H. Substantial Equivalence Information:**

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

Clever Chek Health Care System Software; k070941

2. Comparison with Predicate Device:

<b>Similarities and Differences</b>		
<b>Item</b>	<b>Candidate Andon Health Care Management System</b>	<b>Predicate Clever Chek Health Care System Software (k070941)</b>
Intended Use	Intended for use in home and clinical settings via the internet to assist people with diabetes and their healthcare professionals in uploading, storing, analyzing, and communicating about historical blood glucose test results and other biological statistics to support diabetes management.	Same
Data Use	Data transferred from the device cannot be changed or modified	Same
Meter	For use with Andon AG-608	For use with TaiDoc blood glucose

Compatibility	Single and AG-608 Multi blood glucose meters	meters
Port	Mini USB port	9-pin RS232 port
Installation Method	Exe file	Same
Language capabilities	English, Spanish	English, Spanish, Traditional Chinese
System components	PC, cable, meter	Same
Performance specifications	<ul style="list-style-type: none"> <li>• Reads memory of meter.</li> <li>• Can delete all memory in meter.</li> <li>• Set meter time.</li> <li>• Draw tables and graph.</li> <li>• Print</li> <li>• Set personal information</li> </ul>	Same

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

- EN 61326-1: 2006: Electrical equipment for measurement, control and laboratory use – EMC requirements Part 1: General requirements for safety Collateral standard: Electromagnetic compatibility Requirements and tests- Edition 2.1; Edition 2:2001 consolidated with amendment 1:2004
- EN 61326-2-6: Electrical equipment for measurement, control and laboratory use – EMC requirements Part 2-6: Particular requirements.

**J. Performance Characteristics:**

1. Analytical Performance:

The performance characteristics listed below as applicable, were presented in the specific glucose meter clearance under k093262.

*a. Accuracy:*

See above statement under section J.

*b. Precision/Reproducibility:*

See above statement under section J.

c. *Linearity:*

See above statement under section J.

d. *Carryover:*

See above statement under section J.

e. *Interfering Substances:*

See above statement under section J.

2. Other Supportive Instrument Performance Data Not Covered Above:

- a) The sponsor conducted bench testing for full memory download and rollover for data accuracy using the AG-608 Single/Multi blood glucose meter and confirmed that data were transferred accurately in both tests and no other problems were detected.
- b) A usability study was performed with 20 lay-user participants and 20 professional participants with varying demographics (age, sex, and education level) were included in a usability study. Those study participants also completed a questionnaire in response to whether the data transmission feature is easy to use. The sponsor concluded that the user's responses indicated that data transmission function was easy to operate by following the instructions provided with the system.
- c) The sponsor provided a readability study and obtained SMOG Grade Level Score of 8<sup>th</sup> grade or below for the Andon Health Care Management System Software user guide and the user manuals for the AG-608 Single and AG-608 Multi Blood Glucose Monitoring Systems.
- d) 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.
- e) The sponsors provided the appropriate documentation certifying that electromagnetic testing (EMC) had been performed and the AG-608 Single/Multi meter was found compliant (EN 61326, EN 61326-2-6).
- f) Infection Control Studies: The devices are intended for single-patient use (AG-608 Single) or multiple-patient use (AG-608 Multi). Disinfection efficacy studies were performed on the materials comprising the meters and lancing device by an outside commercial testing demonstrating complete inactivation of hepatitis B virus (HBV) with the chosen disinfectant,

CaviWipes (EPA Registration # 46781-8). Robustness studies were also performed by the sponsor demonstrating that there was no change in performance or external materials for each of the meters and lancing device after 11,000 cleanings and 11,000 disinfection steps with CaviWipes. The robustness studies were designed to simulate 3 years of multiple-patient use and 5 years of single-patient use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

**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.