



AUG 21 2012

### 510(k) Summary K120921

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of SMDA and 21 CFR 807.92.

#### **1.0 Submitter's information**

Simple Diagnostics

11555 Heron Bay Blvd., Suite 200

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Contact: Muhammad Arif, President, Phone (877) 342-2385

Date of Prepared: 06/10/2012

#### **2.0 Device information**

Trade names: (Multiple Models)

Clever Choice Voice+ S; Clever Choice Voice+ M; Clever Choice+ S; Clever Choice+ M

Common name: Blood Glucose Monitoring System

#### **3.0 Classification**

Production code: NBW- Blood Glucose Monitoring System.

Regulation number: 862.1345

Classification: Class II

Classification name: Blood Glucose Monitoring System

Panel: Clinical Chemistry

#### **4.0 Predicate device information**

Manufacturer: Andon Medical Co., Ltd.

Device: AG-6951 Single Blood Glucose Monitoring System

AG-6951 Multi Blood Glucose Monitoring System

510(k) number: K101307

#### **5.0 Device description**

Clever Choice Voice+ S Blood Glucose Monitoring System (BGMS) consists of a blood glucose meter, single use test strips, and the control solutions.

Clever Choice Voice+ M Blood Glucose Monitoring System (BGMS) consists of a blood glucose meter, multi use test strips, and the control solutions.

The four blood Glucose Monitoring system models are all based on an electrochemical biosensor technology (electrochemical) and the principle of capillary action. Capillary action at the end of the test strip draws the blood into the action chamber and the blood glucose result is displayed in 5 seconds. The control solution available is used to test the performance of the device. All of them use the same technological characteristics for testing with their predicate device. The appearance is different from their predicate device. The new Blood Glucose Monitoring Systems have a function of ejecting the used test strip, which is also different from their predicate device.

## **6.0 Intended use (for all four models)**

6.1 The Clever Choice Voice+ S Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertip, palm, forearm, upper arm, calf and thigh. The Clever Choice Voice + S Blood Glucose Monitoring System is to be used by a single person and should not be shared. The Clever Choice Voice+ S 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 Clever Choice Voice+ S Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes, nor for neonatal use. Alternative site testing should be done only during steady– state times (when glucose is not changing rapidly). The Clever Choice Blood Glucose Test +S Test Strips are for use with the Clever Choice Voice+ S Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, upper arm, calf and thigh. The Clever Choice Glucose Controls are intended for in vitro diagnostic use (i.e. for external use only) by healthcare professionals and in the home by people with diabetes mellitus to assess the performance of the Clever Choice Voice+ S meters and Clever Choice +S Test Strips.

6.2 The Clever Choice Voice+ M Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertip, palm, forearm, upper arm, calf and thigh. The Clever Choice Voice + M Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) and is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of a diabetes control program. The Clever Choice Voice + M Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes, nor for neonatal use. Alternative site testing such as the palm, forearm, upper arm, calf and thigh should be done only during steady – state times (when glucose is not changing rapidly). The Clever Choice Blood Glucose +M Test Strips are for use with the Clever Choice Voice+ M Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, upper arm, calf and thigh. The Clever Choice Glucose Controls are intended for in vitro diagnostic use (i.e. for external use only) by healthcare professionals and in the home by people with diabetes mellitus to assess the performance of the Clever Choice Voice+ M meters and Clever Choice +M Test Strips. Only auto-disabling, single use lancing devices may be used with this device.

6.3 The Clever Choice+ S Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertip, palm, forearm, upper arm, calf and thigh. The Clever Choice+ S Blood Glucose Monitoring System is to be used by a single person and should not be shared. The Clever Choice+ S 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 Clever Choice+ S Blood Glucose Monitoring System should not be used for the diagnosis of or screening for

diabetes, nor for neonatal use. Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly). The Clever Choice +S Blood Glucose Test Strips are for use with the Clever Choice+ S Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, upper arm, calf and thigh. The Clever Choice Glucose Controls are intended for in vitro diagnostic use (i.e. for external use only) by healthcare professionals and in the home by people with diabetes mellitus to assess the performance of the Clever Choice+ S meters and Clever Choice +S Test Strips.

6.4 The Clever Choice Voice+ M Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertip, palm, forearm, upper arm, calf and thigh. The Clever Choice+ M Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) and is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of a diabetes control program. The Clever Choice Voice+ M Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes, nor for neonatal use. Alternative site testing such as the palm, forearm, upper arm, calf and thigh should be done only during steady-state times (when glucose is not changing rapidly). The Clever Choice +M Blood Glucose Test Strips are for use with the Clever Choice+ M Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, upper arm, calf and thigh. The Clever Choice Glucose Controls are intended for in vitro diagnostic use (i.e. for external use only) by healthcare professionals and in the home by people with diabetes mellitus to assess the performance of the Clever Choice+ M meters and Clever Choice +M Test Strips. Only auto-disabling, single use lancing devices may be used with this device.

**7.0 Summary comparing technological characteristics with predicate device**

| CHARACTERISTICS                | PREDICATE:<br>AG-6951 Single and Multi Blood<br>Glucose Monitoring System<br>(K101307) | NEW DEVICES:<br>Clever Choice Voice+ S<br>Clever Choice Voice+ M<br>Clever Choice+ S<br>Clever Choice+ M<br>Single and Multi Blood Glucose<br>Monitoring Systems |
|--------------------------------|--|--|
| Detection Method               | Amperometry  | Amperometry  |
| Enzyme                         | Glucose Oxidase  | Glucose Oxidase  |
| Type of Meter                  | Biosensor (Electrode)  | Biosensor (Electrode)  |
| Sample Source                  | Capillary whole blood from<br>AST(Alternative site testing) and<br>finger              | Capillary whole blood from<br>AST(Alternative site testing) and<br>finger  |
| Sample Application             | Blood sample is placed directly to<br>the test strip after finger is lanced.           | Blood sample is placed directly to<br>the test strip after finger or AST is<br>lanced.   |
| Hematocrit Range               | 20-60%   | 20-60%   |
| Operating Temperature<br>Range | 10°C~40°C(50°-104°F)   | 10°C~40°C(50°-104°F)   |
| Dimensions                     | 52mmx 92mmx 21mm   | 102mmx58mm x22mm   |
| Display                        | LCD  | LCD  |

| <b>CHARACTERISTICS</b> | <b>PREDICATE:<br/>AG-6951 Single and Multi Blood<br/>Glucose Monitoring System<br/>(K101307)</b> | <b>NEW DEVICES:<br/>Clever Choice Voice+ S<br/>Clever Choice Voice+ M<br/>Clever Choice+ S<br/>Clever Choice+ M<br/>Single and Multi Blood Glucose<br/>Monitoring Systems</b> |
|------------------------|--|---|
| Result Presentation    | mg/dL or mmol/L  | mg/dL or mmol/L   |
| Memory Capabilities    | 500 times with time and date displaying  | 500 times with time and date displaying   |
| Test Start             | Automatic  | Automatic   |
| Test Time              | 5 second   | 5 second  |
| Power Source           | DC 3V (CR2032)   | DC 3V (CR2032)  |
| Battery Life           | Approx. 500 normal tests   | Approx. 500 normal tests  |
| Measurement Range      | 20mg/dL-600mg/dL<br>(1.1mmol/L~33.3mmol/L)   | 20mg/dL-600mg/dL<br>(1.1mmol/L~33.3mmol/L)  |
| Qualified Test Strip   | AGS-1100 Test Strip  | Clever Choice Test Strip  |
| Sample Volume          | Minimum 0.7 micro liter  | Minimum 0.7 micro liter   |
| Other function         | USB function.<br>Voice function  | USB function.<br>Voice function (or non-voce models)<br>Eject the used test strip   |

### **8.0 Performance summary**

Clever Choice Voice+ S, Clever Choice Voice+ M, Clever Choice+ S, and the Clever Choice+ M Single and Multi blood glucose monitoring systems conform to the following standards:

ISO 15197: In vitro diagnostic test systems- Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus.

Non-clinical test and clinical testing was done according to the above standard.

### **9.0 Comparison to the predict device and the conclusion**

Clever Choice Voice+ S (Single) is similar to the predicate device AG-6951 Single, the two devices are both for single person use, they use the same test strip, and can test the blood glucose at the alternative site. The hematocrit range, the altitude, the memory capability, the battery life and the use function are all the same. Only the appearance is different, and Clever Choice Voice+ S (Single) adds a function of ejecting the used test strip. The Clever Choice S omits the voice function.

Clever Choice Voice+ M (Multi) is similar to the predicate device AG-6951 Multi, the two devices are both for multi person use, they use the same test strip, and can test the blood glucose at the alternative site. The hematocrit range, the altitude, the memory capability, the battery life and the use function are all the same. Only the appearance is different, and Clever Choice Voice+ M Multi adds a function of ejecting the used test strip.

However, the test in this submission provides demonstration that these small differences do not raise any new questions of safety and effectiveness. The Clever Choice M omits the voice function.



Simple Diagnostics  
c/o Daniel Kamm  
Kamm & Associates  
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Naples, FL 34114

10903 New Hampshire Avenue  
Silver Spring, MD 20993

AUG 21 2012

Re: k120921

Trade/Device Name: Clever Choice Voice+ S Blood Glucose Monitoring System  
Clever Choice + S Blood Glucose Monitoring System  
Clever Choice Voice+ M Blood Glucose Monitoring System  
Clever Choice + M Blood Glucose Monitoring System

Regulation Number: 21 CFR 862.1345

Regulation Name: Glucose test system

Regulatory Class: Class II

Product Code: NBW, CGA, JJX

Dated: August 10, 2012

Received: August 17, 2012

Dear Mr. Kamm:

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

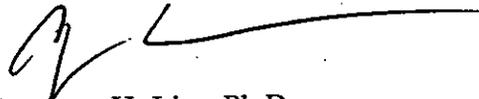
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. 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) 796-5680 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>

Sincerely yours,



Courtney H. Lias, Ph.D.  
Director  
Division of Chemistry and Toxicology Devices  
Office of *In Vitro* Diagnostic Device  
Evaluation and Safety  
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K120921

Device Name: Clever Choice Voice+ S Blood Glucose Monitoring System

## Indications For Use:

The Clever Choice Voice+ S Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertip, palm, forearm, upper arm, calf and thigh. The Clever Choice Voice + S Blood Glucose Monitoring System is to be used by a single person and should not be shared.

The Clever Choice Voice+ S 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 Clever Choice Voice+ S Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes, nor for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly).

The Clever Choice +S Blood Glucose Test Strips are for use with the Clever Choice Voice+ S Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, upper arm, calf and thigh.

The Clever Choice Glucose Controls are intended for in vitro diagnostic use (i.e. for external use only) by healthcare professionals and in the home by people with diabetes mellitus to assess the performance of the Clever Choice Voice+ S meters and Clever Choice +S Test Strips.

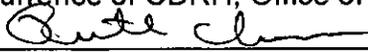
Prescription Use   
(21 CFR Part 801 Subpart D)

And/Or Over the Counter Use   
(21 CFR Part 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

  
Division Sign-Off  
Office of In Vitro Diagnostic Device  
Evaluation and Safety  
510(k) K120921

# Indications for Use

510(k) Number (if known): K120921

Device Name: Clever Choice Voice+ M Blood Glucose Monitoring System

## Indications For Use:

The Clever Choice Voice+ M Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertip, palm, forearm, upper arm, calf and thigh. The Clever Choice Voice+ M Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) and is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of a diabetes control program.

The Clever Choice Voice+ M Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes, nor for neonatal use. Alternative site testing such as the palm, forearm, upper arm, calf and thigh should be done only during steady – state times (when glucose is not changing rapidly).

The Clever Choice +M Blood Glucose Test Strips are for use with the Clever Choice+ M Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, upper arm, calf and thigh.

The Clever Choice Glucose Controls are intended for in vitro diagnostic use (i.e. for external use only) by healthcare professionals and in the home by people with diabetes mellitus to assess the performance of the Clever Choice Voice+ M meters and Clever Choice +M Test Strips.

Only auto-disabling, single use lancing devices may be used with this device.

Prescription Use   
(21 CFR Part 801 Subpart D)

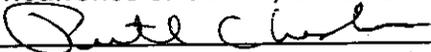
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Over the Counter Use   
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510(k) K120921

# Indications for Use

510(k) Number (if known): K120921

Device Name: Clever Choice+ S Blood Glucose Monitoring System

## Indications For Use:

The Clever Choice+ S Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertip, palm, forearm, upper arm, calf and thigh. The Clever Choice+ S Blood Glucose Monitoring System is to be used by a single person and should not be shared.

The Clever Choice+ S 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 Clever Choice+ S Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes, nor for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly).

The Clever Choice +S Blood Glucose Test Strips are for use with the Clever Choice+ S Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, upper arm, calf and thigh.

The Clever Choice Glucose Controls are intended for in vitro diagnostic use (i.e. for external use only) by healthcare professionals and in the home by people with diabetes mellitus to assess the performance of the Clever Choice+ S meters and Clever Choice +S Test Strips.

Prescription Use   
(21 CFR Part 801 Subpart D)

And/Or Over the Counter Use   
(21 CFR Part 801 Subpart C)

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510(k) K120921

# Indications for Use

510(k) Number (if known): K120921

Device Name: Clever Choice+ M Blood Glucose Monitoring System

## Indications For Use:

The Clever Choice Voice+ M Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertip, palm, forearm, upper arm, calf and thigh. The Clever Choice + M Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) and is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of a diabetes control program.

The Clever Choice Voice+ M Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes, nor for neonatal use. Alternative site testing such as the palm, forearm, upper arm, calf and thigh should be done only during steady – state times (when glucose is not changing rapidly).

The Clever Choice Blood +M Glucose Test Strips are for use with the Clever Choice+ M Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, upper arm, calf and thigh.

The Clever Choice Glucose Controls are intended for in vitro diagnostic use (i.e. for external use only) by healthcare professionals and in the home by people with diabetes mellitus to assess the performance of the Clever Choice+ M meters and Clever Choice +M Test Strips.

Only auto-disabling, single use lancing devices may be used with this device.

Prescription Use   
(21 CFR Part 801 Subpart D)

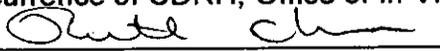
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Over the Counter Use   
(21 CFR Part 801 Subpart C)

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