

# 510(k) Summary

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

The Assigned 510(k) number is k103044

## 1. Submitter's Identification

Bestgen Biotech Corporation  
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## 2. Device Name

Proprietary name: AP-1010, AP-1010multi, AP-1020, and AP-1020multi Blood Glucose Monitoring System

Regulatory information:

- A. Regulation section: 21 CFR Section 862.1345 Glucose Test System  
21 CFR Section 862.1660, Quality Control Material
- B. Classification: Class II for 862.1345  
Class I for 862.1660
- C. Product Code: CGA, Glucose Oxidase, Glucose  
NBW, System, Test, Blood Glucose, Over The Counter
- D. Panel: Chemistry (75)

## 3. Intended Use

AP-1010 Blood Glucose Monitoring System

The AP-1010 Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger. The AP-1010 Blood Glucose Monitoring System is intended to be used by a single person and should not be shared. The AP-1010 Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as aid to monitor the effectiveness of diabetes control. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

The AP-1010 Blood Glucose Test Strips are intended for the quantitative measurement of glucose in fresh

capillary whole blood sample drawn from the fingertips. AP-1010 Blood Glucose Test Strips must be used with the AP-1010 Blood Glucose Meter. Testing is done outside the body (In Vitro diagnostic use). It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

#### AP-1010multi Blood Glucose Monitoring System

The AP-1010multi Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger. The AP-1010multi Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) and is intended for multi-patient use in professional healthcare settings as an aid to monitor the effectiveness of diabetes control program. This system should only be used with single-use lancing devices. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

The AP-1010multi Blood Glucose Test Strips are intended for the quantitative measurement of glucose in fresh capillary whole blood sample drawn from the fingertips. AP-1010multi Blood Glucose Test Strips must be used with the AP-1010multi Blood Glucose Meter. Testing is done outside the body (In Vitro diagnostic use). This system should only be used with single-use lancing devices. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

#### AP-1020 Blood Glucose Monitoring System

The AP-1020 Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger. The AP-1020 Blood Glucose Monitoring System is intended to be used by a single person and should not be shared. The AP-1020 Blood Glucose Monitoring Systems is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as aid to monitor the effectiveness of diabetes control. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

The AP-1020 Blood Glucose Test Strips are intended for the quantitative measurement of glucose in fresh capillary whole blood sample drawn from the fingertips. AP-1020 Blood Glucose Test Strips must be used with the AP-1020 Blood Glucose Meter. Testing is done outside the body (In Vitro diagnostic use). It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

#### AP-1020multi Blood Glucose Monitoring System

The AP-1020multi Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger. The AP-1020multi Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) and is intended for multi-patient use in professional healthcare settings as an aid to monitor the effectiveness of diabetes control program. This system should only be used with single-use lancing devices. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

The AP-1020multi Blood Glucose Test Strips are intended for the quantitative measurement of glucose in fresh capillary whole blood sample drawn from the fingertips. AP-1020multi Blood Glucose Test Strips must be used with the AP-1020multi Blood Glucose Meter. Testing is done outside the body (In Vitro diagnostic use). This system is only used with single-use lancing devices. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

#### 4. Device Description

The AP-1010 Blood Glucose Monitoring System consists of three main products: the meter, test strip, and control solutions. These products have been designed, tested, and proven to work together as a system accurate blood glucose test results. Use only AP-1010 test strips and MAJOR control solution with the AP-1010 Blood Glucose Monitoring System.

The AP-1010multi Blood Glucose Monitoring System consists of three main products: the meter, test strip, and control solutions. These products have been designed, tested, and proven to work together as a system accurate blood glucose test results. Use only AP-1010multi test strips and MAJOR control solution with the AP-1010multi Blood Glucose Monitoring System.

The AP-1020 Blood Glucose Monitoring System consists of three main products: the meter, test strip, and control solutions. These products have been designed, tested, and proven to work together as a system accurate blood glucose test results. Use only AP-1020 test strips and MAJOR control solution with the AP-1020 Blood Glucose Monitoring System.

The AP-1020multi Blood Glucose Monitoring System consists of three main products: the meter, test strip, and control solutions. These products have been designed, tested, and proven to work together as a system accurate blood glucose test results. Use only AP-1020multi test strips and MAJOR control solution with the AP-1020multi Blood Glucose Monitoring System.

#### 5. Substantial Equivalence Information

A. Predicate device name:

AP-1000 Blood Glucose Monitoring System

B. Predicate K number: k090389

C. Comparison with predicate:

The modified AP-1010, AP-1010multi, AP-1020, and AP-1020multi Blood Glucose Monitoring System have the following similarities to the predicate device:

- same operating principle,
- same fundamental scientific technology,
- incorporate the same basic circuit design,
- incorporate the same materials,
- same shelf life
- same software validation
- packaged using the same materials, and
- manufactured by same process

The modifications encompass:

- engineering change in the mechanical appearance of the device and name change

#### 6. Test Principle

The detection and measurement of glucose in blood is by an electrochemical biosensor technology

using glucose oxidase.

## **7. Performance Characteristics**

AP-1010, AP-1010multi, AP-1020, and AP-1020multi Blood Glucose Monitoring System has the same performance characteristics as the predicate device.

Software verification and validation testing confirmed that the performance, safety and effectiveness of the AP-1010, AP-1010multi, AP-1020, and AP-1020multi Blood Glucose Monitoring System are equivalent to the predicate device.

## **8. Conclusion**

Based on the information provided in this submission, the AP-1010, AP-1010multi, AP-1020, and AP-1020multi Blood Glucose Monitoring System is substantially equivalent to the predicate AP-1000 Blood Glucose Monitoring System.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

FEB 10 2012

Re: k103044

Trade/Device Name: AP-1010/AP-1010multi and AP-1020/AP-1020multi Blood Glucose  
Monitoring Systems

Regulation Number: 21 CFR 862.1345

Regulation Name: Glucose test system.

Regulatory Class: II

Product Code: NBW, CGA

Dated: December 16, 2011

Received: December 16, 2011

Dear Mr. Shen:

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 either class II (Special Controls) or class III (PMA), 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).

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

## Indication for Use

510(k) Number (if known): k103044

Device Name: AP - 1010 Blood Glucose Monitoring System

### Indication For Use:

The AP - 1010 Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger. The AP - 1010 Blood Glucose Monitoring System is intended to be used by a single person and should not be shared. The AP - 1010 Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as aid to monitor the effectiveness of diabetes control. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

The AP - 1010 Blood Glucose Test Strips are intended for the quantitative measurement of glucose in fresh capillary whole blood sample drawn from the fingertips. AP - 1010 Blood Glucose Test Strips must be used with the AP - 1010 Blood Glucose Meter. Testing is done outside the body (In Vitro diagnostic use). It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

Prescription Use \_\_\_\_\_  
(21 CFR Part 801 Subpart D)

And/Or

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

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

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) k103044

510(k) Number (if known): k103044

Device Name: AP-1010multi Blood Glucose Monitoring System

Indication For Use:

The AP - 1010multi Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger. The AP - 1010multi Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) and is intended for multi - patient use in professional healthcare settings as an aid to monitor the effectiveness of diabetes control program. This system should only be used with single - use lancing devices. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

The AP - 1010multi Blood Glucose Test Strips are intended for the quantitative measurement of glucose in fresh capillary whole blood sample drawn from the fingertips. AP - 1010multi Blood Glucose Test Strips must be used with the AP - 1010multi Blood Glucose Meter. Testing is done outside the body (In Vitro diagnostic use). This system should only be used with single - use lancing devices. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

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(21 CFR Part 801 Subpart D)

And/Or

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Evaluation and Safety

510(k) k103044

510(k) Number (if known): k103044

Device Name: AP-1020 Blood Glucose Monitoring System

The AP - 1020 Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger. The AP - 1020 Blood Glucose Monitoring System is intended to be used by a single person and should not be shared. The AP - 1020 Blood Glucose Monitoring Systems is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as aid to monitor the effectiveness of diabetes control. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

The AP - 1020 Blood Glucose Test Strips are intended for the quantitative measurement of glucose in fresh capillary whole blood sample drawn from the fingertips. AP - 1020 Blood Glucose Test Strips must be used with the AP - 1020 Blood Glucose Meter. Testing is done outside the body (In Vitro diagnostic use). It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

Prescription Use \_\_\_\_\_  
(21 CFR Part 801 Subpart D)

And/Or

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

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Evaluation and Safety

510(k) k103044

510(k) Number (if known): k103044

Device Name: AP-1020multi Blood Glucose Monitoring System

The AP - 1020multi Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger. The AP - 1020multi Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) and is intended for multi - patient use in professional healthcare settings as an aid to monitor the effectiveness of diabetes control program. This system should only be used with single - use lancing devices. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

The AP - 1020multi Blood Glucose Test Strips are intended for the quantitative measurement of glucose in fresh capillary whole blood sample drawn from the fingertips. AP - 1020multi Blood Glucose Test Strips must be used with the AP - 1020multi Blood Glucose Meter. Testing is done outside the body (In Vitro diagnostic use). This system is only used with single - use lancing devices. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

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