510(k) Summary

APR 2 4 2012

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 k103230

1. Submitter's Identification

Bestgen Biotech Corporation
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2. Device Name

Proprietary name: AP-3000 and AP-3000multi 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 JJX, Quality Control Material (assayed and unassayed)
D. Panel:	Chemistry (75)

3. Intended Use

3.1 AP-3000 Blood Glucose Monitoring System

The AP-3000 Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and from the alternative sites (palm, forearm, upper arm, calf, and thigh) for self testing by persons with diabetes at home. The AP-3000 Blood Glucose Monitoring Systems is intended for testing outside the body (in vitro diagnostic use). It is intended for use by lay users and should only be used by a single patient as an aid to monitor the effectiveness of diabetes control. It is intended to be used by a single person and should not be shared. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

The AP-3000 Meter is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and from the alternative sites (palm, forearm, upper arm, calf, and thigh) for self testing by persons with diabetes at home. AP-3000 Blood Glucose Test Strips must be used with the AP-3000 Meter. The AP-3000 Meter is intended for testing outside the body (in vitro diagnostic use). It is intended for use by lay users and should only be used by a single patient as an aid to monitor the effectiveness of diabetes control. It is intended to

be used by a single person and should not be shared. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

The AP-3000 Blood Glucose Test Strips are intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and from the alternative sites (palm, forearm, upper arm, calf, and thigh) for self testing by persons with diabetes at home. AP-3000 Blood Glucose Test Strips must be used the AP-3000 Blood Glucose Meter. The AP-3000 Blood Glucose Test Strips are intended for testing outside the body (in vitro diagnostic use). It is intended for use by lay users and should only be used by a single patient as an aid to monitor the effectiveness of diabetes control. It is intended to be used by a single person and should not be shared. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

MAJOR Level I/Level II Control Solution is for use with AP-3000 meter and AP-3000 Blood Glucose Test Strips as a quality control check to verify the accuracy of blood glucose test results.

3.2 AP-3000multi Blood Glucose Monitoring System

The AP-3000multi Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and from the alternative sites (palm, forearm, upper arm, calf, and thigh) for self testing by persons with diabetes. The AP-3000multi Blood Glucose Monitoring Systems is intended for testing outside the body (in vitro diagnostic use). It is intended for multi-patient use in a professional healthcare setting, as an aid to monitor the effectiveness of diabetes control. This system is only used with single-use, auto-disabling 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-3000multi Meter is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and from the alternative sites (palm, forearm, upper arm, calf, and thigh) for self testing by persons with diabetes. AP-3000multi Blood Glucose Test Strips must be used with the AP-3000multi Meter. AP-3000multi Meter is intended for testing outside the body (in vitro diagnostic use). It is intended for multi-patient use in a professional healthcare setting, as an aid to monitor the effectiveness of diabetes control. This system is only used with single-use, auto-disabling 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-3000multi Blood Glucose Test Strips are intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and from the alternative sites (palm, forearm, upper arm, calf, and thigh) for self testing by persons with diabetes. AP-3000multi Blood Glucose Test Strips must be used with the AP-3000multi Meter. AP-3000multi Blood Glucose Test Strips are intended for testing outside the body (in vitro diagnostic use). It is intended for multi-patient use in a professional healthcare setting, as an aid to monitor the effectiveness of diabetes control. This system is only used with single-use, auto-disabling lancing devices. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

MAJOR Level I/Level II Control Solution is for use with AP-3000multi meter and AP-3000multi Blood Glucose Test Strips as a quality control check to verify the accuracy of blood glucose test results.

4. Device Description

The AP-3000 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-3000 test strips and MAJOR control solution with the AP-3000 Blood Glucose Monitoring System.

The AP-3000multi 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-3000multi test strips and MAJOR control solution with the AP-3000multi 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 new device of AP-3000/AP-3000multi Blood Glucose Monitoring System has the following similarities to the predicate device:

Similarities		
Item	Device (AP-3000/AP-3000multi BGMS)	Predicate (AP-1000 BGMS, k090389)
Detection Method	Amperometry	Amperometry
Enzyme	Glucose Oxidase (Aspergillus niger)	Glucose Oxidase (Aspergillus niger)
Test Range	20-600 mg/dL	20-600 mg/dL
Temperature Range	50 ~ 104°F (10 ~ 40°C)	50 ~ 104°F (10 ~ 40°C)
Open Use Time (Strip)	90 days	90 days
Coding	Internal Code Selection	Internal Code Selection

Differences		
Item	Device (AP-3000/AP-3000multi BGMS)	Predicate (AP-1000 BGMS, k090389)
Meter Size	55mm x 88mm x26mm	54mm x 93mm x 16 mm
Meter Weight	65 g (with battery)	53 g (with battery)
Strip Ejection	Yes	No
LCD with Backlight	Yes	No
Memory Capability	488 measurements	960 measurements
Power	Two AAA batteries	One CR2032 3V lithium battery
Humidity Range	< 85%	20~80%
Testing Time	7 seconds	6 seconds
Sample Volume	0.7 μL	0.6 μL
Sample Source	The glucose concentration is measured with quantitative capillary whole blood from the fingertip, palm, forearm, upper arm, calf, and thigh.	The glucose concentration is measured with quantitative capillary whole blood from the fingertip.
HCT Range	20-60%	30-55%

6. Test Principle

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

7. Performance Characteristics

The performance of AP-3000/AP-3000multi Blood Glucose Monitoring System was studied in the laboratory and in clinical settings by healthcare professionals and lay users. The studies demonstrated that the performance of this system meets its intended use.

8. Conclusion

Based on the information provided in this submission, the AP-3000/AP-3000multi Glucose Monitoring System is substantially equivalent to the predicate AP-1000 Blood Glucose Monitoring System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

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Silver Spring, MD 20993

Bestgen Biotech Corporation
c/o Mr. Steven Shen
Quality Assurance Manager
7F., No. 186, Jian-Yi Road, Jung-He City
Taipei, Taiwan, 235, ROC

APR 2 4 2012

Re: k103230
Trade Name: AP-3000 Blood Glucose Monitoring System
AP-3000multi Blood Glucose Monitoring System
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: CGA, NBW, JJX
Dated: April 19, 2012
Received: April 23, 2012

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

Indications for Use

510(k) Number: k103230

Device Name: AP-3000 Blood Glucose Monitoring System

Indications for Use:

The AP-3000 Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and from the alternative sites (palm, forearm, upper arm, calf, and thigh) for self testing by persons with diabetes at home. The AP-3000 Blood Glucose Monitoring Systems is intended for testing outside the body (in vitro diagnostic use). It is intended for use by lay users and should only be used by a single patient as an aid to monitor the effectiveness of diabetes control. It is intended to be used by a single person and should not be shared. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

The AP-3000 Meter is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and from the alternative sites (palm, forearm, upper arm, calf, and thigh) for self testing by persons with diabetes at home. AP-3000 Blood Glucose Test Strips must be used with the AP-3000 Meter. The AP-3000 Meter is intended for testing outside the body (in vitro diagnostic use). It is intended for use by lay users and should only be used by a single patient as an aid to monitor the effectiveness of diabetes control. It is intended to be used by a single person and should not be shared. 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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MAJOR Level I/Level II Control Solution is for use with AP-3000 meter and AP-3000 Blood Glucose Test Strips as a quality control check to verify the accuracy of blood glucose test results.

Prescription Use_____ And/Or Over the Counter Use___V___

(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

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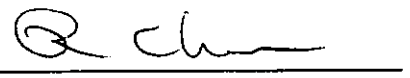
Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)



Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k103230

Indications for Use

510(k) Number: k103230

Device Name: AP-3000mutli Blood Glucose Monitoring System

Indications for Use:

The AP-3000multi Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and from the alternative sites (palm, forearm, upper arm, calf, and thigh) for self testing by persons with diabetes. The AP-3000multi Blood Glucose Monitoring Systems is intended for testing outside the body (in vitro diagnostic use). It is intended for multi-patient use in a professional healthcare setting, as an aid to monitor the effectiveness of diabetes control. This system is only used with single-use, auto-disabling 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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MAJOR Level I/Level II Control Solution is for use with AP-3000multi meter and AP-3000multi Blood Glucose Test Strips as a quality control check to verify the accuracy of blood glucose test results.

Prescription Use V And/Or Over the Counter Use V

(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

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