510(k) Summary

(a) (1) Submitter's name, address
Bionostics, Inc.
7 Jackson Road
Devens, MA 01432

Contact Person
Randy Byrd
VP, Chief Technical Officer
(978) 772-7070 x 272

Date of preparation of this summary: 19 February 2013

(2) Device trade or proprietary name: GlucoseMeter-Check Solution for Roche ACCU-CHEK

Device common or usual name or classification name:
75 JJX, single (specified) analyte controls (assayed and unassayed)

CLASSIFICATION
REGULATION NAME NUMBER CLASS PRODUCT CODE
Quality Control Material 862.1660 I, reserved JJX

(3) Substantial Equivalence
Glucose Meter-Check Solution is substantially equivalent in function, safety and efficacy to the currently marketed device for the same intended use:

Comparison of Glucose Meter-Check Solution to predicate device for substantial equivalency

<table>
<thead>
<tr>
<th>Similarities and Differences of the Blood Glucose Control</th>
<th>Predicate Device</th>
<th>Candidate Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intended Use/Indications for Use</td>
<td>Glucose Meter-Check Solution Roche ACCU-CHEK is intended to assess the performance of the following Roche ACCU-CHEK blood glucose monitoring systems: Roche ACCU-CHEK Aviva® and ACCU-CHEK Aviva Combo® using Aviva Plus® test strips Roche ACCU-CHEK Active® using ACCU-CHEK Active test strips Roche ACCU-CHEK Compact® and ACCU-CHEK Compact Plus® using ACCU-CHEK Compact test strips Roche ACCU-CHEK Advantage using Comfort Curve® test strips</td>
<td>Same, with the addition of Roche Nano SmartView using SmartView test strips.</td>
</tr>
</tbody>
</table>
Similarities and Differences of the Blood Glucose Control, continued

<table>
<thead>
<tr>
<th>Item</th>
<th>Predicate Device K081403</th>
<th>Candidate Device K123851</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stability</td>
<td>24 Months</td>
<td>same</td>
</tr>
<tr>
<td>Value assignment</td>
<td>determined by analysis of glucose on commercial lots of glucose test strips qualified for proper measurement using manufacturer recommended control solution</td>
<td>same</td>
</tr>
<tr>
<td>Traceability</td>
<td>N.I.S.T. SRM 917</td>
<td>same</td>
</tr>
<tr>
<td>Target range</td>
<td>90 to 112 mg/dL (range of midpoint value assignment for various meter types)</td>
<td>108 to 147 mg/dL (range of midpoint value assignment for various meter types)</td>
</tr>
<tr>
<td>Auto QC detection</td>
<td>no</td>
<td>yes, for Nano and Aviva BGMS no, for Active, Compact Plus and Advantage BGMS</td>
</tr>
<tr>
<td>Matrix</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ingredient (w/v%)</td>
<td>Current Solution</td>
<td>Ingredient (w/v%)</td>
</tr>
<tr>
<td>High Purity Water</td>
<td>91.6</td>
<td>High Purity Water</td>
</tr>
<tr>
<td>Buffers</td>
<td>1.0</td>
<td>Buffers</td>
</tr>
<tr>
<td>Salts</td>
<td>0.5</td>
<td>Salts</td>
</tr>
<tr>
<td>Viscosity Modifier</td>
<td>6.6</td>
<td>Viscosity Modifier</td>
</tr>
<tr>
<td>Glucose</td>
<td>0.10</td>
<td>Glucose</td>
</tr>
<tr>
<td>Preservatives</td>
<td>0.05</td>
<td>Preservatives</td>
</tr>
<tr>
<td>Dyes</td>
<td>0.08</td>
<td>Dyes</td>
</tr>
<tr>
<td>Container</td>
<td>6 mL white LDPE</td>
<td>same</td>
</tr>
<tr>
<td>Analyte</td>
<td>glucose</td>
<td>same</td>
</tr>
<tr>
<td>Color</td>
<td>red</td>
<td>same</td>
</tr>
<tr>
<td>Net Fill</td>
<td>4 mL</td>
<td>same</td>
</tr>
</tbody>
</table>

*midpoint of assigned values, depending on meter and test strip combination

(4) Description of the new device

Glucose Meter-Check Solution is a single-level, viscosity-adjusted, aqueous liquid glucose control solution. Glucose Meter-Check Solution is intended for use to verify the performance of the Roche ACCU-CHEK brand BGM Systems listed in the package insert at recover glucose values within the interval 2 recommended in ISO 15197:2003 in vitro diagnostic test systems – Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus for most meter types (Aviva, SmartView, Advantage), and comparable to solutions currently marketed by Roche for others (Active, Compact). This mid-level glucose concentration will complement the current, low and high glucose concentrations available in quality control products distributed by Roche Diagnostics for these same BGM systems. The product is packaged in plastic bottles with dropper tips for application of the solution to test strips. The control has a red color to help users see the solution while dispensing onto a test strip.
Glucose Meter-Check Solution is a non-hazardous aqueous solution glucose control solution containing no ingredients of biological origin, or in concentrations qualifying as a controlled product under the Controlled Products Regulation.

Standard/Guidance Documents Referenced (if applicable):
- ISO 14971:2009 Medical devices – Application of risk management to medical devices
- ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General Requirements
- ISO 18113-4 In vitro diagnostic medical devices - Information supplied by the manufacturer (labeling) - Part 4: In vitro diagnostic reagents for self-testing
- EN 13640 Stability Testing of In Vitro Diagnostic Reagents
- Guidance for Industry and FDA Staff – Assayed and Unassayed Quality Control Material

(5) Intended use of the device
Glucose Meter-Check Solution Roche ACCU-CHEK is intended to assess the performance of the following Roche ACCU-CHEK blood glucose monitoring systems:

- Roche ACCU-CHEK Nano SmartView® using SmartView® test strips
- Roche ACCU-CHEK Aviva® and ACCU-CHEK Aviva Combo® using Aviva Plus® test strips
- Roche ACCU-CHEK Active® using ACCU-CHEK Active test strips
- Roche ACCU-CHEK Compact® and ACCU-CHEK Compact Plus® using ACCU-CHEK Compact test strips.
- Roche ACCU-CHEK Advantage using Comfort Curve® test strips

Glucose Meter-Check Solution for Roche ACCU-CHEK is intended for use by healthcare professionals and people with diabetes mellitus at home.

(6) Technological characteristics of the device.
This material consists of viscosity-adjusted, aqueous glucose control solution prepared with a single concentration of D-glucose and has been optimized to simulate the response of whole blood on the Roche ACCU-CHEK blood glucose monitoring systems. The solution contains no hazardous, human or animal derived components. The solution is recognized as a control automatically by the ACCU-CHEK Aviva and Nano SmartView meters to perform consistently as the Roche branded products.

Test Principle:
The BGMS with which this control solution is utilized utilize enzymatic measurement of glucose
(b) (1) Summary of non-clinical tests submitted with the premarket notification for the device.
Tests were conducted to verify specific performance requirements:

a) Value assignment process:
For 3 lots of test strips evaluated for each meter type, 8 measurements of the Glucose Meter-Check Solution on each of 5 meters providing 120 measurements of Glucose Meter-Check on each meter type.

Because the precision performance of the control solution on a blood glucose test system is primarily determined by the composition of the test strips, we assign the acceptable range of measurement as ± 15% to correspond to the value assignment ranges currently provided by Roche for the meters using the Roche appropriate ACCU-CHEK test strips. Each meter and strip combination is considered to be operating correctly if all measurements of Roche ACCU-CHEK branded control solutions are recovered within the assay ranges provided on each carton of test strips. Value assignment resulting from the grand mean of all measurements on each meter type (all strip lots) was considered valid if at least 95% of individual values obtained are within the assigned range provided for each lot of test strips.

b) Closed bottle stability: Stability characteristics were determined under un-opened conditions in real-time stability studies of equivalent product to demonstrate an unopened shelf-life of 2 years (24 months) at the recommended storage temperatures, ranging from 2°C to 30°C (36°F to 86°F) as measured by YSI 2300 calibrated with N.I.S.T. 917 traceable materials.

c) Stability after opening: Glucose Meter-Check Solution for Bayer meets stability requirements as demonstrated by less than 5% change in percent glucose recovery on YSI on vials evaluated of 3 months (93 days).

d) Method comparison with predicate device
To evaluate equivalence\(^1\), we performed a series of measurements at room temperature on two meters of each brand using the Glucose Meter-Check Solution followed by one level of Roche ACCU-CHEK branded control solution appropriate for each test strip brand.

As an example, the Nano blood glucose meter was evaluated with one measurement of Glucose Meter Check Solution on each of two meters using one lot of test strips, followed by one measurement of SmartView control solution on each meter. This sequence was repeated until 25 sets of pairs were recorded. The entire process of value assignment and evaluation of equivalence elapsed over several testing days.

The individual values obtained on each measurement were compared to the relevant value assignment ranges for each test strip lot as well as to the value assignment ranges determined\(^2\) for the Meter-Check control solution calculated as mean recovered from

\(^1\) BIOVR-1175 Evaluation of Equivalence – Glucose Meter-Check\(^*\) Solution for Roche ACCU-CHEK Blood Glucose Meters, Rev. A

\(^2\) BIOVR-1176 Value Assignment for Glucose Meter-Check\(^*\) Solution for Roche ACCU-CHEK Blood Glucose Monitoring Systems, Rev. A.
measurement on three (3) test strip lots ± 15% to correspond to the value assignment ranges currently utilized by Roche for the meters using SmartView test strips.

Detailed results are provided in Table 2: Summary Results of Control Performance Equivalence on the following page. Each quality control solution was measured in series as described above on each of the Infopia test systems.

The Acceptance Criteria (at least 95% of measurements obtained for the manufacturer recommended quality control solution were within the value assignment ranges provided on the test strips for that meter, test strip and control solution combination) were met with 100% of all values recovered within value assignment ranges provided with each vial of test strips. 100% of Meter Check measurements on the same meter and test strip combination were within the value assignment ranges established for Meter Check.

<table>
<thead>
<tr>
<th>Test Strip Type</th>
<th>Meter Brand</th>
<th>Control Brand</th>
<th>Pooled Mean (mg/dL)</th>
<th>Pooled SD</th>
<th>Pooled CV%</th>
<th>assay range (mg/dL)</th>
<th>assay range (%)</th>
<th>within assay range</th>
</tr>
</thead>
<tbody>
<tr>
<td>SmartView</td>
<td>Nano</td>
<td>SmartView</td>
<td>122.0</td>
<td>1.8</td>
<td>1.5%</td>
<td>116 - 128</td>
<td>15%</td>
<td>100%</td>
</tr>
<tr>
<td></td>
<td>SmartView</td>
<td>Current Meter-Check</td>
<td>109.8</td>
<td>2.0</td>
<td>1.8%</td>
<td>105 - 115</td>
<td>15%</td>
<td>100%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>New Meter-Check</td>
<td>108.9</td>
<td>1.8</td>
<td>1.6%</td>
<td>92 - 124</td>
<td>15%</td>
<td>100%</td>
</tr>
<tr>
<td>Aviva Plus</td>
<td>Aviva</td>
<td>Aviva</td>
<td>46.6</td>
<td>0.6</td>
<td>1.2%</td>
<td>30 - 60</td>
<td>15mg/dL</td>
<td>100%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Current Meter-Check</td>
<td>110.2</td>
<td>1.3</td>
<td>1.2%</td>
<td>85 - 115</td>
<td>15%</td>
<td>100%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>New Meter-Check</td>
<td>111.8</td>
<td>1.2</td>
<td>1.0%</td>
<td>92 - 124</td>
<td>15%</td>
<td>100%</td>
</tr>
<tr>
<td>Compact</td>
<td>Compact, Compact Plus</td>
<td>Compact Blue</td>
<td>204.4</td>
<td>2.8</td>
<td>1.4%</td>
<td>186 - 252</td>
<td>15%</td>
<td>100%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Current Meter-Check</td>
<td>90.7</td>
<td>2.3</td>
<td>2.6%</td>
<td>82 - 111</td>
<td>15%</td>
<td>100%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>New Meter-Check</td>
<td>146.2</td>
<td>3.4</td>
<td>2.3%</td>
<td>125 - 169</td>
<td>15%</td>
<td>100%</td>
</tr>
<tr>
<td>Active</td>
<td>Active</td>
<td>Active</td>
<td>171.3</td>
<td>2.3</td>
<td>1.3%</td>
<td>154 - 207</td>
<td>15%</td>
<td>100%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Current Meter-Check</td>
<td>112.9</td>
<td>2.6</td>
<td>2.3%</td>
<td>95 - 129</td>
<td>15%</td>
<td>100%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>New Meter-Check</td>
<td>176.4</td>
<td>3.6</td>
<td>2.0%</td>
<td>150 - 202</td>
<td>15%</td>
<td>100%</td>
</tr>
<tr>
<td>Comfort Curve</td>
<td>Advantage</td>
<td>Comfort Curve</td>
<td>57.9</td>
<td>2.5</td>
<td>4.4%</td>
<td>44 - 74</td>
<td>15mg/dL</td>
<td>100%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Current Meter-Check</td>
<td>82.8</td>
<td>2.6</td>
<td>3.1%</td>
<td>76 - 103</td>
<td>15%</td>
<td>100%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>New Meter-Check</td>
<td>105.7</td>
<td>2.9</td>
<td>2.7%</td>
<td>94 - 127</td>
<td>15%</td>
<td>100%</td>
</tr>
</tbody>
</table>

Table 2: Summary Results of Control Performance Equivalence

This evaluation demonstrates the new Meter-Check solution is equivalent to both the currently marketed Meter-Check Solution cleared under K081403, and to the Roche ACCU-CHEK branded control solution recommended for use with each of these test systems.

(b) (2) Summary of clinical tests submitted with the premarket notification for the device.
N/A

(b) (3) Conclusions drawn from the clinical and non-clinical trials.
Comparison of technological characteristics, formulation and intended use to predicate devices listed in this summary support the claim of substantial equivalence.
February 14, 2013

Bionostics, Inc  
c/o Randy Byrd  
7 Jackson Road  
Devens, MA 01434

Re: k123851  
Trade/Device Name: Glucose Meter-Check Solution for Roche ACCU-CHEK  
Regulation Number: 21 CFR 862.1660  
Regulation Name: Quality control material  
Regulatory Class: I, reserved  
Product Code: JJX  
Dated: December 13, 2012  
Received: December 17, 2012

Dear Mr. Byrd:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to [http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm](http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm) for
the Center for Devices and Radiological Health’s (CDRH’s) Office of Compliance. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21CFR Part 807.97). 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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure
Indications for Use

510(k) Number (if known): k123851

Device Name: Glucose Meter-Check Solution for Roche ACCU-CHEK

Indications for Use:

Glucose Meter-Check Solution Roche ACCU-CHEK is intended to assess the performance of the following Roche ACCU-CHEK blood glucose monitoring systems:

- Roche ACCU-CHEK Nano SmartView® using SmartView® test strips
- Roche ACCU-CHEK Aviva® and ACCU-CHEK Aviva Combo® using Aviva Plus® test strips
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Glucose Meter-Check Solution for Roche ACCU-CHEK is intended for use by healthcare professionals and people with diabetes mellitus at home.

For In Vitro Diagnostic Use

Prescription Use __X__ And/Or Over the Counter Use __X__
(21 CFR Part 801 Subpart D) (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 Diagnostics and Radiological Health (OIR)

Katherine Serrano
Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k123851