



AGAMATRIX, INC.
DAVID OLSEN
VP QUALITY & REGULATORY AFFAIRS
7C RAYMOND AVE.
SALEM NH 03079

November 30, 2016

Re: K161834
Trade/Device Name: One Drop Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, CGA
Dated: November 01, 2016
Received: November 02, 2016

Dear Mr. David Olsen:

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 Parts 801 and 809); 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 regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education 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>. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR 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 Industry and Consumer Education 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,

Katherine Serrano -S

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)

K161834

Device Name

One Drop Blood Glucose Monitoring System

Indications for Use (Describe)

The One Drop Blood Glucose Monitoring System is intended for the quantitative measurement of blood glucose (sugar) levels in fresh capillary whole blood samples drawn from the fingertip. It is intended to be used by a single patient and should not be shared. The One Drop 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 One Drop Blood Glucose Monitoring System is not for the diagnosis of, or screening for diabetes, and is not intended for use with neonates.

The One Drop Blood Glucose Test Strips:

The One Drop Blood Glucose Test Strips are for use with the One Drop Blood Glucose Meter to quantitatively measure blood glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510 (k) Section 15

510(k) Summary Rev. 092716

This summary of 510(k) substantial equivalence is being submitted in accordance with the requirements of 21 CFR 807.92.

1. **Prepared:** June 29, 2016
2. **Submitter:** AgaMatrix, Inc.
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Phone: (603) 328-6000
4. **Contact:** David M. Olsen
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dolsen@agamatrix.com
Phone: 603-328-6049
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5. **Device Name:** Trade/Proprietary Name: One Drop Blood Glucose Monitoring System
Common Name: Glucose Test System

6. Device Classification:

Product Code	Classification	Regulation	Pan
CGA – glucose Oxidase	Class II	21 CFR 862.1345	75, Clinical Chemistry
NBW – system, test, blood glucose, over the counter	Class II	21 CFR 862.1345	75, Clinical Chemistry

7. Predicate Device:

AgaMatrix Jazz Wireless 2 Blood Glucose Monitoring System, 510(k) K152365

8. Device Description:

The One Drop Blood Glucose Monitoring System (BGMS) is intended for the quantitative measurement of blood glucose levels in fresh capillary whole blood samples drawn from the fingertip. It is intended to be used by a single patient and should not be shared. The One Drop BGMS 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 System is not for the diagnosis of, or screening for diabetes, and is not intended for use with neonates.

The system measures the concentration of glucose in a drop of blood obtained from the fingertip. The test strip is inserted into the meter and the blood is then introduced to the tip of the test strip. The blood reacts with chemicals on the test strip and this reaction generates an electrical current which is measured by the meter. The magnitude of the current is related to the blood glucose concentration. The fundamental scientific technology and the electronics that sends the electrical signals to the assay algorithm are all the same as the predicate device AgaMatrix Jazz Wireless 2 BGMS (K152365). The unit of measure displayed on the meter screen is fixed in mg/dL and cannot be modified by the user.

The One Drop Blood Glucose Monitoring System (BGMS) consists of:

- 1 One Drop Blood Glucose Meter
- 1 One Drop Owner's Guide
- 1 Carry Case
- 1 Lancing Device
- 10 Lancets
- 100 One Drop Glucose Test Strips
- AgaMatrix Glucose Control Solution (available separately)

9. Intended Use & Indications for Use:

9.1. Intended Use:

Blood Glucose Monitoring

9.2. Indications for Use:

The One Drop Blood Glucose Monitoring System is intended for the quantitative measurement of blood glucose (sugar) levels in fresh capillary whole blood samples drawn from the fingertip. It is intended to be used by a single patient and should not be shared. The One Drop 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 One Drop Blood Glucose Monitoring System is not for the diagnosis of, or screening for diabetes, and is not intended for use with neonates.

The One Drop Blood Glucose Test Strips are for use with the One Drop Blood Glucose Meter to quantitatively measure blood glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

10. Comparison to Predicate

Similarities		
Item	Predicate Device	Candidate Device
	<p>AgaMatrix Jazz Wireless 2 Blood Glucose Monitoring System (K152365)</p>	<p>One Drop Blood Glucose Monitoring System</p>
<p>Intended Use/Indications for Use</p>	<p>The AgaMatrix Jazz Wireless 2 Blood Glucose Monitoring System is intended for the quantitative measurement of blood glucose levels in fresh capillary whole blood samples drawn from the fingertip. It is intended to be used by a single patient and should not be used for testing multiple patients. The AgaMatrix Jazz Wireless 2 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 AgaMatrix Jazz Wireless 2 Blood Glucose Monitoring System is not for the diagnosis of or screening for diabetes, and is not intended for use with neonates.</p> <p>The AgaMatrix Jazz Wireless 2 Blood Glucose Test Strips are for use with the AgaMatrix Jazz Wireless 2 Glucose Meter to quantitatively measure blood glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.</p>	<p>The One Drop Blood Glucose Monitoring System is intended for the quantitative measurement of blood glucose levels in fresh capillary whole blood samples drawn from the fingertip. It is intended to be used by a single patient and should not be used for testing multiple patients. The One Drop 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 One Drop Blood Glucose Monitoring System is not for the diagnosis of or screening for diabetes, and is not intended for use with neonates.</p> <p>The One Drop Blood Glucose Test Strips are for use with the One Drop Blood Glucose Meter to quantitatively measure blood glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.</p> <p style="text-align: center;">(Same as Predicate)</p>

Similarities		
Item	Predicate Device AgaMatrix Jazz Wireless 2 Blood Glucose Monitoring System (K152365)	Candidate Device One Drop Blood Glucose Monitoring System
Sample Type	Capillary whole blood	Same
Sample Sites	Finger tip	Same
Sample Volume	0.5 µL	Same
Average Test Time	5 seconds	Same
Test range	20 - 600 mg/dL	Same
Operating Temperature	50° - 104°F	Same
Measurement Range	20 to 600 mg/dL	Same
Calibration	Plasma Equivalent	Same
Control Levels	Two Levels	Same
Operating Humidity	10% to 90%	Same
Hematocrit Range	20 - 60%	Same
Altitude Study	Up to 10,000 feet	Same

Similarities		
Item	Predicate Device AgaMatrix Jazz Wireless 2 Blood Glucose Monitoring System (K152365)	Candidate Device One Drop Blood Glucose Monitoring System
Power Source	(2) replaceable CR2032 3 volt, lithium batteries	Same
Connectivity	Meter can send BGM results via Bluetooth to smart devices using the appropriate iOS or Android software application.	Same
Detection method	Dynamic Electrochemistry	Same
Enzyme	Glucose Oxidase	Same
Calibration Coding	Non-Coding	Same

Differences		
Item	Predicate Device	Candidate Device
	AgaMatrix Jazz Wireless 2 Blood Glucose Monitoring System (K152365)	One Drop Blood Glucose Monitoring System
Meter size	L-2.56 inches, H-0.39 inches	L-2.76inches, H-0.47inches
Weight	18g	20g
Meter Outer Finish	ABS polymer blend with color pigment added to polymer	ABS polymer blend covered with an aluminum plating

11. Technological Characteristics:

The device modifications described in this premarket notification do not affect or alter the fundamental scientific technology of the predicate device, the AgaMatrix Jazz Wireless 2 Blood Glucose Monitor.

12. Intended Use:

The modifications described in this premarket notification do not alter or change the intended use of the modified device from its predicate the AgaMatrix Jazz Wireless 2 Blood Glucose Monitor.