K101597

AgaMatrix

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## 510(k) SAFETY AND EFFECTIVENESS SUMMARY

OCT 18 2010

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

1. Submitter's Name, Address, Telephone Number, Contact Person, and date the summary was prepared.

| | |
|---|---|
| Submitter's Name: | AgaMatrix, Inc. |
| Address: | 10 Manor Parkway<br>Salem, NH 03079<br>(603) 328-6000 |
| Contact Person: | Connie Hertel<br>Director Quality & Regulatory Affairs<br>chertel@agamatrix.com |
| Date the summary prepared: | August 31, 2010 |

2. Device Name

| | |
|---|---|
| Trade/Proprietary Name: | AgaMatrix WaveSense Diabetes Manager |
| Common/Usual Name: | WaveSense Diabetes Manager |
| Classification Name: | None |
| Class | unclassified |

| | |
|---|---|
| Trade/Proprietary Name: | AgaMatrix WaveSense BGM meters |
| Common/Usual Name: | AgaMatrix WaveSense BGM meters |
| Classification Name: | NBW, JQP |
| Class | II |

3. Predicate Device

Zero-Click Data Management System
510(k) number: k062434

4. Device Description

The WaveSense Diabetes Manager (WDM) application (app) is a digital logbook and diabetes management tool for the iPhone operating system platform. The application can be used alone or with the WaveSense Direct Connect Cable and a WaveSense-enabled Blood Glucose Meter (BGM) with a mini-USB port.

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5. Intended Use:

The AgaMatrix WaveSense Diabetes Manager (WDM) application (app) is intended for use in the home and professional settings to aid individuals with diabetes and their healthcare professionals: in the review, analysis and evaluation of blood glucose test results to support an effective diabetes management program. It is an optional data management software accessory for use with the WaveSense-enabled blood glucose meter (BGM) with a mini-USB port. The WaveSense Diabetes Manager allows users to download Blood glucose reading automatically from the meter to an iPhone Operating System platform.

6. Assessment of Performance:

An evaluation of the WaveSense Diabetes Manager was studied in house and in a Clinical setting by persons with diabetes. The studies demonstrated the ease of operating the WaveSense Diabetes Manager application as intended.

7. Comparison to Predicate device

| | Zero-Click Data Management Software | WaveSense Diabetes Management Application |
|---|---|---|
| Intended Use | The AgaMatrix WaveSense Diabetes Manager (WDM) application (app) is intended for use in the home and professional settings to aid individuals with diabetes and their healthcare professionals: in the review, analysis and evaluation of blood glucose test results to support an effective diabetes management program | same |
| Accessory to | WaveSense Blood Glucose Monitoring Meters | same |
| Log book for | Blood glucose readings | Blood glucose readings and Insulin and Carbohydrates intake |
| Use on | PC | iPhone Operating System platform |

**8. Conclusions**

The results of clinical evaluations of the WaveSense Diabetes Manager application demonstrate that the application is equivalent in performance to the predicate device and suitable for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Agamatrix
c/o Connie Hertel
10 Maor Parkway,
Salem, NH 03079

OCT 18 2010

Re: k101597
Trade/Device Name: WaveSense Diabetes Manager application
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system.
Regulatory Class: II
Product Code: NBW, JQP
Dated: September 22, 2010
Received: September 24, 2010

Dear: Ms. Hertel:

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

Enclosure

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# Indications for Use

**510(k) Number (if known):** K101597

**Device Name:** WaveSense Diabetes Manager application

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**Indications for Use:**

The WaveSense Diabetes Manager (WDM) application (app) is intended for use in the home and professional settings to aid individuals with diabetes and their healthcare professionals; in the review, analysis and evaluation of blood glucose readings to support an effective diabetes management program. The WaveSense Diabetes Manager application is a digital logbook and diabetes management tool designed to operate using the iPhone Operating System platform. The application can be used alone or with the WaveSense Direct Connect Cable and a WaveSense-enabled blood glucose meter (BGM) with a mini-USB port.

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
K101597