June 6, 2024

AgaMatrix
Dave Valcourt
Regulatory Affairs Manager
7C Raymond Ave
Salem, New Hampshire 03079

Re: K241304
Trade/Device Name: WaveSense Jazz Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW
Dated: May 9, 2024
Received: May 9, 2024

Dear Dave Valcourt:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Joshua Balsam -S

Joshua M. Balsam, Ph.D.
Branch Chief
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241304

Device Name

WaveSense Jazz Blood Glucose Monitoring System

Indications for Use *(Describe)*

The WaveSense Jazz Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood from the finger stick, palm and/or forearm. Testing is done outside of the body (in vitro diagnostic use). It is indicated for use at home (over the counter (OTC)) by persons with diabetes, as an aid to monitor the effectiveness of diabetes control.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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) Summary

Prepared on: 2024-06-04

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	AgaMatrix
Applicant Address	7C Raymond Ave Salem NH 03079 United States
Applicant Contact Telephone	603-328-6079
Applicant Contact	Dave Valcourt
Applicant Contact Email	dvalcourt@agamatrix.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	WaveSense Jazz Blood Glucose Monitoring System
Common Name	Blood Glucose Monitoring System
Classification Name	System, Test, Blood Glucose, Over the Counter
Regulation Number	862.1345
Product Code(s)	NBW

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K072413	WaveSense Jazz Blood Glucose Monitoring System	NBW

Device Description Summary

21 CFR 807.92(a)(4)

The WaveSense Jazz Blood Glucose Monitoring System includes a meter with batteries, compact carrying case, lancing device lancets, control solution and instructions for use. Test Strips are necessary for testing but are sold separately.

The WaveSense Jazz Blood Glucose Monitoring System is intended for the quantitative measurement of blood glucose levels in fresh capillary whole blood samples drawn from the fingertips, palm or forearm. The WaveSense Jazz Test Strips are for in vitro diagnostic (outside of the body) use only. The WaveSense Jazz System is not intended for use with neonates.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The WaveSense Jazz Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood from the finger stick, palm and/or forearm. Testing is done outside of the body (in vitro diagnostic use). It is indicated for use at home (over the counter (OTC)) by persons with diabetes, as an aid to monitor the effectiveness of diabetes control.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use of the candidate device are the same as the indications for use of the predicate device with the following changes: the candidate device is not indicated for prescription use and is not indicated for clinical use.

Technological Comparison

21 CFR 807.92(a)(6)

The candidate WaveSense Jazz BGMS has the same fundamental scientific technology as the predicate WaveSense Jazz BGMS. The differences between the candidate WaveSense Jazz BGMS and the predicate are the introduction of new colors on the top housing and the introduction of a new data management feature.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Activities to verify and validate the modification included: disinfection and robustness testing, firmware functional testing and usability engineering evaluations.

Based on the verification and validation results, the candidate WaveSense Jazz Blood Glucose Monitoring System is substantially equivalent to the predicate WaveSense Jazz Blood Glucose Monitoring System (K072413).