Vibrant Reporter Software
Regulatory Strategy

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Note: The content in this presentation does not have any confidential information

Agenda

1. Introduction
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4. Predicate Device Comparison
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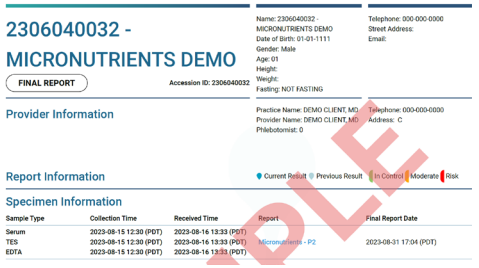
1. Introduction

- **Device Name: Vibrant Reporter Software (SaMD - Software as Medical Device)**
- **Intended Use:** Software to process and report results from Vibrant laboratory-developed tests (food sensitivity, micronutrient, and gut microbiome).
- **Regulatory Class (U.S.):** Class II DeNovo (Confirm with FDA as part of Q-Sub Meeting)
- **Applicable FDA Regulations: Confirm actual regulation after meeting with FDA**
  - 21 CFR 862.2100 - Calculator/data processing module for clinical use. – Potentially Class I
  - 21 CFR Part 862 – Clinical Chemistry and Clinical Toxicology Devices
  - 21 CFR Part 866 – Immunology and Microbiology Devices
  - 21 CFR Part 809 – In Vitro Diagnostic Products for Human Use
- **Pathway**: Class II (510(k) DeNovo pathway) – post-analytical reporting software. FDA may not agree to 21 CFR Part 862.2100
- **Regulatory Strategy**:
  - Position Vibrant Reporter as an adjunctive reporting tool, not a diagnostic device.
  - Leverage clinical validation from Vibrant Wellness assays (food sensitivity, micronutrients, microbiome) to support claims.
  - Mitigation of higher regulatory burden by framing scope around workflow automation and post-analytical reporting, avoiding direct diagnostic/treatment claims.

Intended Use



Vibrant Reporter software is designed to analyze and interpret raw data files produced by laboratory instruments, which includes real-time polymerase chain reaction (RT-PCR) instruments, mass-spectrometry instruments, microarray scanners instruments and chemiluminescence instruments. It processes data derived from human specimens by applying validated algorithms for each test and converts it into reportable test results. It displays the test results and associated annotations from clinical information from public literature, databases and internal performance studies. The Vibrant Reporter software supports workflow automation for transfer of test results and associated annotations to external systems, such as Laboratory Information Systems (LIS).

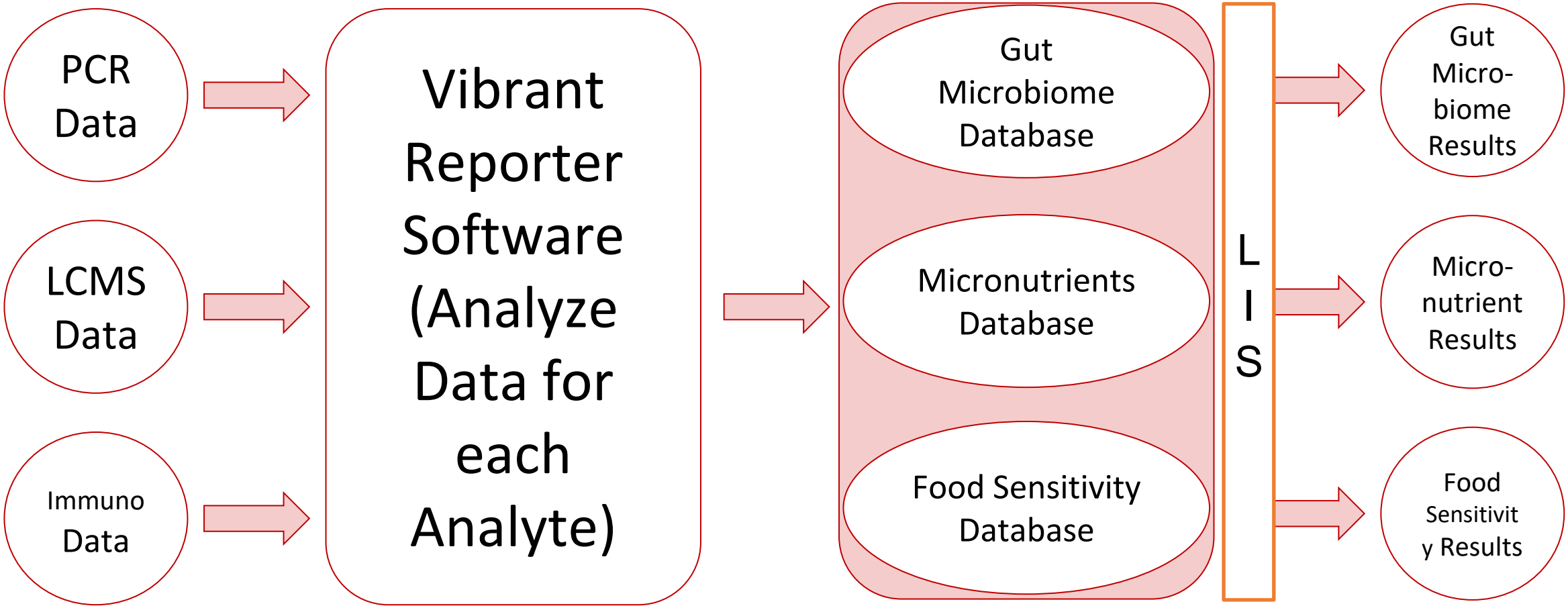
The Vibrant Reporter software is intended for use by qualified laboratory personnel within accredited laboratories. The Vibrant Reporter software validation as part of the test post analytical workflow is the responsibility of the laboratory. Final interpretation of test results and any diagnostic or treatment decisions remain the responsibility of qualified healthcare professionals.

Note: Potentially US FDA 862.2100 Calculator/data processing module for clinical use.(a) Identification. A calculator/data processing module for clinical use is an electronic device intended to process laboratory data.(b) Classification. Product codes JQP and NVV. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9. EU review MCDG Guidance and consult notified body.

Intended Use Details

- **Software Function:** Vibrant Reporter analyzes raw output files from laboratory instruments (RT-PCR, microarray, mass spectrometry, chemiluminescence).
- **Scope of Testing:**
  - **Food Sensitivity:** IgG/IgE antibody-based assays
  - **Micronutrients:** Spectrometry-based quantification of vitamins & minerals
  - **Gut Microbiome:** Sequencing/PCR-based profiling of microbial communities
- **Process:**
  - Applies validated algorithms specific to each Vibrant Wellness test
  - Converts raw data into structured, reportable results
  - Adds clinical annotations from literature, databases, and internal validation studies
- **End Users:**
  Qualified laboratory personnel within accredited laboratories
- **Limitations:**
  - Not a standalone diagnostic tool
  - Final interpretation and clinical decision-making remain with licensed healthcare professionals

Vibrant Reporter Software Process Workflow



2. Executive Summary

Purpose: Enables accredited labs to analyze and report test results from Vibrant Wellness assays.

Scope: Food sensitivity, micronutrients, gut microbiome.

Key Value:

- Streamlines reporting workflow for lab staff
- Provides consistent annotations from validated databases and literature
- Supports integration with LIS (Laboratory Information Systems)

Limitations: Adjunctive tool only; final interpretation remains with qualified healthcare providers.

3. Product Description

Inputs: Raw data from RT-PCR, microarray, mass-spectrometry, and chemiluminescence assays.

Process:

- Applies validated algorithms for each Vibrant Wellness test.
- Normalizes, analyzes, and interprets results.
- Annotates with literature-based evidence and clinical references.

Outputs: Structured, reportable results with annotations.

End-Users: Qualified laboratory personnel in accredited labs.

4. Predicate Device Comparison

Feature	Vibrant Reporter	Predicate Devices	Difference
Intended Use	Reports Vibrant Wellness test results (food sensitivity, micronutrients, microbiome)	**JQP:** i-STAT Central Data Station (Flextronics); DxOne Workflow Manager (Beckman) **NVV:** LIS modules for data storage/transfer (Hitachi Cobas)	Vibrant = IVD reporting; Predicates = workflow/data handling
Input Data	RT-PCR, microarray, mass spec, chemiluminescence	**JQP:** Analyzer data, QC tracking **NVV:** LIS and automation data	Vibrant = broader IVD lab data
Output	Structured reports + clinical annotations	**JQP:** Data aggregation, workflow reports **NVV:** Storage & transfer only	Vibrant adds annotations & literature context
Regulatory Path	Class II, 510(k) De Novo, EU MDR IIa	**JQP:** Class I, 510(k)-exempt **NVV:** Class I, 510(k)-exempt	Vibrant = higher regulatory oversight
End Users	Accredited lab personnel	Lab operators, LIS managers	Similar users; different scope

5. Method Comparison / Performance Study (Analytical)

Food Sensitivity: ELISA/antibody-based test data interpreted into IgG-mediated sensitivity results.

Micronutrients: Mass spectrometry data normalized against control standards; validated accuracy through internal clinical performance studies.

Gut Microbiome: Next-generation sequencing (NGS) and RT-PCR profiling, converted into diversity and abundance reports.

Validation Approach:

- Internal lab validation against known controls
- Cross-referenced with published literature and databases
- Software verified for accuracy, reproducibility, and workflow reliability

6. Regulatory Risks and Mitigations

Risk	Potential Impact	Mitigation Strategy
Misinterpretation of food sensitivity, micronutrient, or microbiome results	Incorrect clinical use; potential harm if used as diagnostic	Limit software to reporting role; clear disclaimers in IFU; final interpretation left to healthcare professionals
Algorithm drift or annotation errors	Inaccurate reporting; loss of clinical reliability	Continuous validation per ISO 5338 & ISO 13485; periodic re-verification against reference datasets
Data integrity & cybersecurity breaches	Compromised results; patient privacy violations	Encrypted data transfer, secure storage, role-based access controls, audit trails
Misuse as standalone diagnostic tool	Regulatory non-compliance; increased liability	Labeling restrictions, explicit limitations in user manuals and training materials
Lack of LIS (Laboratory Information System) interoperability	Workflow delays, manual errors in transferring results	HL7/FHIR compliance, validated LIS integration, interface testing
Inadequate traceability of test data and results	Failure in audits, inability to demonstrate compliance	Implement audit trails, version control, electronic records compliance (21 CFR Part 11)

6. 510(k) DeNovo Submission Contents

1	Medical Device User Fee Cover Sheet (Form FDA 3601) CDRH Premarket Review Submission	12	Substantial Equivalence Discussion
2	Cover Sheet	13	Proposed Labeling
3	510(k) Cover Letter	14	Sterilization and Shelf Life
4	Indications for Use Statement	15	Biocompatibility
5	510(k) Summary or 510(k) Statement	16	Software
6	Truthful and Accuracy Statement	17	Electromagnetic Compatibility and Electrical Safety
7	Class III Summary and Certification	18	Performance Testing – Analytical
8	Financial Certification or Disclosure Statement	19	~~Performance Testing – Animal~~
9	Declarations of Conformity and Guidance Documents	20	Performance Testing – Clinical
10	Executive Summary	21	Other
11	Device Description		

6. EU Summary Technical Documentation Submission Contents

DermaScan Summary Technical Documentation

Appendix A – Labeling
Appendix B – Regulatory Classification
Appendix C – Design Information
Appendix D – Manufacturing
Appendix E – GSPR Checklist
Appendix F – Risk Management
Appendix G – Performance Evaluation
Appendix H – Stability Data
Appendix I – Software Documentation
Appendix J – Additional Data
Appendix K – Post Market Surveillance
Appendix L – Declaration of Conformity

7. Regulatory Approval Timeline