Section 5.0 510(k) Summary - MATCH IT! ® Antibody software version 1.5

5.1 Submitter

Owner/Manufacturer:	Immucor GTI Diagnostics, Inc.
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Date Prepared:	8-30-2022

5.2 Name Of Device

Device Trade Name:	MATCH IT! ® Antibody version 1.5
Common Name:	MATCH IT! ® Antibody software
Classification Name:	Test, Qualitative, For HLA, Non-Diagnostic
Division:	CBER
Review Panel:	Hematology
Product Code:	MZI
Classification:	Unclassified
Submission Type:	Special 510(k)

Regulatory Class (Device Class): Class II

5.3 Name Of Predicate Device For Claiming Equivalence

MATCH IT! ® Antibody software 1.4 (BK210572)

5.4 Device Description

MATCH IT!® Antibody software is an optional accessory to aid in the evaluation of test results from Immucor GTI Diagnostics, Inc. LIFECODES® Antibody detection kits for use with Luminex. Due to the complex nature of HLA Testing, qualified laboratory personnel must review any result to ensure correctness.

The software is a computer program designed to analyze the raw data coming from the Luminex Fluoroanalyzer after running the LIFECODES® Antibody assays. The software consists of one installation USB device, a User's Manual and a Quick Reference Guide. Install Instructions and Release notes are also available.

Applicable LIFECODES® Antibody detection kits are listed in the MATCH IT!® Antibody software Quick Reference Guide.

The MATCH IT!® Antibody software is designed to analyze the raw data coming from the Luminex Fluoroanalyzer when used with LIFECODES® Antibody detection Kits. The raw data is in csv file format and consists of the Median Fluorescent Intensity (MFI) values for each bead in an assay. The relative signal (MFI) obtained with the probes/bead in the LIFECODES® assays can be used to assign the probes/bead as having positive or negative reactivity. This in turn provides the information needed to determine antibody assignments. The generated csv files can be imported and the data processed with the MATCH IT!® Antibody software. The calculations and subsequent analysis performed by the software are outlined in the MATCH IT!® Antibody software User's manual and the Instructions for Use of the LIFECODES® Antibody detection Kits.

The MATCH IT!® Antibody software is intended to assist qualified laboratory personnel. Due to the complex nature of HLA Testing, qualified laboratory personnel must review any clinical or diagnostic

result to ensure correctness. The software is a laboratory aid and not meant to be the sole source of a definitive result.

The software consists of one installation USB, Quick Reference guide, and a user's manual.

Proposed Change:
New functionality: LifeScreen XP, Non-HLA (RUO) products, added detailed graph for LSA, and improved epitope analysis functionality.

5.5 INDICATIONS FOR USE

5.5.1 Intended Use:
MATCH IT! Antibody software is an optional accessory to aid in the evaluation of test results from Immucor GTI Diagnostics, Inc. LIFECODES Antibody detection kits for use with Luminex. Due to the complex nature of HLA Testing, qualified laboratory personnel must review any result to ensure correctness.

For *In Vitro* Diagnostic (IVD) Use.

5.5.2 Indications for Use:
MATCH IT! Antibody software v1.5 is an optional accessory to the following LIFECODES antibody detection kits for use with Luminex:

Software Models
The software will include the products described below for each model of the software.

LIFECODES® Class I ID	PN 628200	IFU LC807IVD
LIFECODES® Class II ID v2	PN 628223	IFU LC807IVD
LIFECODES® LifeScreen Deluxe	PN 628215	IFU LC1003IVD
LIFECODES® LSA Class I	PN 265100IVD	IFU LC1683IVD
LIFECODES® LSA Class II	PN 265200IVD	IFU LC1683IVD
LIFECODES® LifeScreen XP	PN 628220	IFU LC1698IVD

Default settings for all assays are aligned with the IFU and the performance characteristics of the assay. Any other methods of assignment would need to be validated by lab personal prior to use.

The software is intended for In vitro diagnostic use.

Documentation to support the software versions are as follows:
1. User Manual; one version
    a. IVD LC1684IVD
2. Quick Reference Guides (QRG)
    a. LC1686EN

The User Manuals and Quick Reference Guides are translated into the languages required for the markets the software is distributed to.

5.6 Substantial Equivalence
The Intended Use of the software is not changing. The software is not intended for prescription or over-the-counter use. The software is used in clinical laboratories where patient, blood donor and transplant associated testing is performed.

Within the submission, the studies performed to verify the modifications made to the MATCH IT! ® Antibody Software are being provided. The modification of the software being presented in this submission is the compilation and verification of new functionality LifeScreen XP, non-HLA products, added detailed graph for LSA, and Improved epitope analysis functionality. Detailed graphs for LSA

and improved epitope analysis functionalities are being added to aid the qualified laboratory in personal in assessing the patterns of reactivity observed. LIFECODES LifeScreen XP is part of LIFECODES LifeScreen Deluxe. XP has two extra beads and functions exactly the same as Deluxe, so there was no need to have a separate section in the manual.

- The proposed revision of the MATCH IT! Antibody Software User Manual Instructions and Quick Reference Guide are provided in the labeling section. The Quick Reference Guide is available to users to supplement the User Manual.
- Clarification of the product name is being provided as MATCH IT!® Antibody Software.

5.6.1 Summary of Similarities and Differences between the MATCH IT! ® Antibody Software v1.4 and the MATCH IT! ® Antibody Software v1.5.

Similarities between the MATCH IT!® Antibody Software v1.4 and the MATCH IT!® Antibody Software v1.5:

- The Intended Use has not changed between versions of the software.
- The algorithm applied to the LifeScreen XP is identical to the existing algorithm for LifeScreen Deluxe. There are no functionality changes that would impact the results supplied by the software.
- LSA graph and epitope analysis tools have been updated. The updated functionality would not impact the results supplied by the software.
- There are no changes to the algorithm applied for the LIFECODES assay products.

Differences between the MATCH IT! ® Antibody Software v1.4 and the MATCH IT!® Antibody Software v1.5:

The changes have been updated as described in the table below.

The table below provides the comparison between the MATCH IT!® Antibody software v1.5 and the predicate device.

#	ELEMENT/ FEATURE	PREDICATE DEVICE	CANDIDATE DEVICE	Comments
1	Trade Name	MATCH IT!® Antibody software v1.4	MATCH IT!® Antibody software v1.5	---
2	Manufacturer	Immucor GTI Diagnostics, Inc.	Immucor GTI Diagnostics, Inc.	---
3	Intended Use	MATCH IT! ® Antibody software v1.4 is an optional accessory to aid in the evaluation of test results from Immucor GTI Diagnostics, Inc. LIFECODES® Antibody detection kits for use with Luminex. Due to the complex nature of HLA Testing, qualified laboratory personnel must review any result to ensure correctness.	MATCH IT! ® Antibody software v1.5 is an optional accessory to aid in the evaluation of test results from Immucor GTI Diagnostics, Inc. LIFECODES® Antibody detection kits for use with Luminex. Due to the complex nature of HLA Testing, qualified laboratory personnel must review any result to ensure correctness.	No Difference
4	Indications for Use	MATCH IT! ® Antibody software v1.4 is an optional accessory to the following LIFECODES	MATCH IT! ® Antibody software v1.5 is an optional accessory to the following LIFECODES	Upgraded Requirement

		antibody detection kits for use with Luminex: LIFECODES® Class I ID LIFECODES® Class II ID v2 LIFECODES® LifeScreen Deluxe LIFECODES® LSA Class I LIFECODES® LSA Class II Default settings for all assays are aligned with the IFU and the performance characteristics of the assay. Any other methods of assignment would need to be validated by lab personal prior to use.	antibody detection kits for use with Luminex: LIFECODES® Class I ID LIFECODES® Class II ID v2 LIFECODES® LifeScreen Deluxe LIFECODES® LSA Class I LIFECODES® LSA Class II LIFECODES LifeScreen XP Default settings for all assays are aligned with the IFU and the performance characteristics of the assay. Any other methods of assignment would need to be validated by lab personal prior to use.	
5	Software Environment	The software is designed to work in a centralized database environment on a network, or in a standalone configuration on your computer.	The software is designed to work in a centralized database environment on a network, or in a standalone configuration on your computer.	No Difference
6	Hardware and Software Minimum Requirements	Microsoft® Windows 10 operating systems	Microsoft® Windows 10 operating systems	No Difference
		.NET Framework Version 4.6 (Included with software)	.NET Framework Version 4.6 (Included with software)	No Difference
		Microsoft® SQL Server 2016 Express (Included with software)	Microsoft® SQL Server 2016 Express (Included with software)	No Difference
		2.33 GHz or faster 64-bit processor	2.33 GHz or faster 64-bit processor	No Difference
		50 GB hard disk space	50 GB hard disk space	No Difference
		8 GB RAM	8 GB RAM	No Difference
		DirectX 9 or later graphics card with WDDM 1.0 driver	DirectX 9 or later graphics card with WDDM 1.0 driver	No Difference
		XGA display with 1024 x 768	XGA display with 1024 x 768	No Difference
		A mouse or other Windows compatible point device	A mouse or other Windows compatible point device	No Difference

		A Windows compatible printer driver	A Windows compatible printer driver	No Difference
7	Data Import Requirements	Designed to import csv files created by the Luminex xPONENT software	Designed to import csv files created by the Luminex xPONENT software	No Difference
		Luminex is running software versions xPONENT 3.1, 4.2, or 4.3	Luminex is running software versions xPONENT 3.1, 4.2, or 4.3	No Difference
		The batch name cannot be reused and cannot exceed 30 characters including spaces.	The batch name cannot be reused and cannot exceed 30 characters including spaces.	No Difference
		The data present in the csv file must be generated using an unmodified Luminex template that is provided by Immucor GTI Diagnostics.	The data present in the csv file must be generated using an unmodified Luminex template that is provided by Immucor GTI Diagnostics.	No Difference
8	Data Analysis	Analyze the raw data and review the results in graphical form.	Analyze the raw data and review the results in graphical form.	No Difference
		Adjust Cut-off values to clarify the results.	Adjust Cut-off values to clarify the results.	No Difference
		Easily update product information	Easily update product information	No Difference
		Search for specific data	Search for specific data	No Difference
9	Reporting	Create standard reports	Create standard reports	No Difference
		Create custom reports	Create custom reports	No Difference
10	UDI	10888234500810	10888234500810	No Difference

Similarities between the MATCH IT! ® Antibody software v1.5 and MATCH IT!® Antibody software v1.4

1. MATCH IT!® Antibody software v1.5 and MATCH IT!® Antibody software v1.4 have same intended use and indications for use.

2. MATCH IT!® Antibody software v1.5 and MATCH IT!® Antibody software v1.4 utilize raw data from the Luminex instrument employing same bead based Luminex Assay technology and same assay steps.

3. MATCH IT!® Antibody software v1.5 and MATCH IT!® Antibody software v1.4 work in the same software environment.

Differences between the MATCH IT!® Antibody software v1.5 and MATCH IT!® Antibody software v1.4

The differences between the predicate device and the candidate device reflect the addition of LIFECODES LifeScreen XP. The algorithm wasn't changed. The advances in the technological capabilities of the subject device reflect the most current technology that exists to allow performance to current industry standards. The new features do not raise any new questions of safety or effectiveness of the subject device when compared to the predicate.

5.7 Comparison Of Technological Characteristics With The Predicate Device (Substantial Equivalence).

Electrical safety and electromagnetic compatibility (EMC):
Luminex's Technical Files include Declarations of Conformity to the ECD (Electromagnetic Compatibility Directive) 86/336/EEC and the LVD (Low Voltage Directive) 73/23/EEC for the Fluoroanalyzer, XYP (96 plate accessory) and sheath delivery system.

Software Verification and Validation Testing:
Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

Nonclinical tests submitted:
Independent nonclinical performance studies are not required for the software as the software cannot be utilized as a stand-alone device.

Clinical tests submitted:
Independent clinical performance studies are not required for the software as the software cannot be utilized as a stand-alone device. Verification of the software to produce the same calculations, as manual methods have been completed for LIFECODES HLA Antibody assays. User Acceptance Testing has also been completed. The software meets the provisions of the standard IEC 62304, Software Life-cycle Processes.

For the prior software version, MATCH IT! Antibody software v1.4, Validations #370 and #475 verified that the software can provide the same results as the manual calculations indicated in the product insert and thus validated the software's intended use.

Software-related Documentation:
The following guidance documents issued by the agency have been referenced during preparation of this Traditional 510(k) submission:

• "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", May 11, 2005.
• "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices", October 2, 2014.
• "Applying Human Factors and Usability Engineering to Medical Devices", February 3, 2016.
• "List of Highest Priority Devices for Human Factors Review", February 3, 2016 (draft guidance).

5.7.1 Content of Pre-Market Submissions for Software Contained in Medical Devices.
The device is categorized as Moderate Concern. The following documentation is being provided related to the device modification being proposed:

Software Documentation	Requirement for Moderate Concern devices	Included Yes/No	Explanation
Level of Concern	A statement indicating the Level of Concern and a description of the rational for that level.	Yes	NA
Software Description	A summary overview of the features and software operating environment	Yes	NA

Risk Management (Device Hazard Analysis)	Tabular description of identified hardware and software hazards, including severity assessment and mitigations	Yes	NA
Software Requirements Specification (SRS)	The complete SRS document	Yes	NA
Architecture Design Chart	Detailed depiction of functional units and software modules. May include state diagrams as well as flow charts.	Yes	NA
Software Design Specification (SDS)	Software design specification document.	Yes	NA
Traceability Analysis	Traceability among requirements, specifications, identified hazards and mitigations, and Verification and Validation testing.	Yes	NA
Software Development Environment Description	Summary of software life cycle development plan, including a summary of the configuration management and maintenance activities.	Yes	NA
Verification and Validation Documentation	The Verification and Validation of the software modification is a part of the Functional, Scenario, UAT and Installation Testing.	Yes	See Functional, Scenario, UAT and Installation Testing.
Revision Level History	Revision history log, including release version number and date.	Yes	NA
Unresolved Anomalies (Bugs or Defects)	List of remaining software anomalies, annotated with an explanation of the impact on safety or effectiveness, including operator usage and human factors.	Yes	NA
Off-the-Shelf Software	Not defined. Include in Software Description.	Yes	NA
Detailed Functional Test Results	Applies to Verification and Validation Documentation.	Yes	NA
Scenario Test Report	Applies to Verification and Validation Documentation.	Yes	NA
User Acceptance Test Documentation	Applies to Verification and Validation Documentation.	Yes	NA
Installation Test Report	Applies to Verification and Validation Documentation.	Yes	NA

5.7.2 Studies supporting safety and effectiveness of the candidate device

MATCH IT!® Antibody software v1.5 is being submitted to be usable on 64-bit computer systems as an IVD product for the US market. Unit testing as described below presents Verification and Validation of the software. The Verification and Validation of the software is a part of the Functional, Scenario, UAT and Installation Testing.

Section 18.0, Performance Testing-Bench presents the Master Test Plan which defines the verification requirements and provides evidence that the MATCH IT!® Antibody was designed, installed, and tested in accordance with its intended use and is in compliance with

quality software engineering principles. The following sub-system test types evaluated individual components of the software:

• Functional Testing
• Scenario Testing
• Full System Testing
• User Acceptance Testing
• Installation Testing

The reports for each of these testing studies are provided in Section 21.0, Software.

5.7.3 Management of Cybersecurity in Medical Devices
The guidance "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices" was used to define the evaluation of cybersecurity threats and vulnerabilities associated with the MATCH IT!® Antibody software v1.5. The following activities were performed:

Vulnerability Assessment of MATCH IT! ® Antibody software and bundled applications

• Threat Modeling
• Cybersecurity Risk Assessment of MATCH IT! ® Antibody software
• Cybersecurity Guidance Document for MATCH IT! ® Antibody software
• MDS2 for MATCH IT! ® Antibody software

A Vulnerability Assessment report identified findings related to MATCH IT!® Antibody software v1.5. The level of risk associated with the findings were categorized as high, medium, low and informational. Cybersecurity Risks identified during the cybersecurity risk assessment are mitigated or reduced using Cybersecurity Controls to an acceptable level.

A Cybersecurity Guidance Document for MATCH IT! ® Antibody software has been prepared which will be provided to users describing steps to implement to reduce cybersecurity risks.

5.7.4. Human Factors and Usability Engineering in Medical Devices
The two guidance documents, listed below, were applied to the Human Factors and Usability Engineering assessment which generated a statement on non-application based on the following points:

• The criteria for requiring the application of a human factors and usability engineering process to a medical device such as the MATCH IT!® Antibody Software product is the possibility of causing serious harm to a patient or user.
• Users performing tasks incorrectly or failing to perform tasks using the MATCH IT!® Antibody software product cannot result in serious harm to the patient or user.
• MATCH IT!® Antibody software is not included on the high priority list of devices.
• Review of five points for consideration of non-high priority list devices, did not identify conditions which would require inclusion in premarket submission.
• The application of a human factors and usability engineering process as defined by the FDA guidance is not required for the MATCH IT!® Antibody software product. Human factors data does not need to be provided in the FDA submission.

Guidance documents applied to Human Factors and Usability Assessment

Applying Human Factors and Usability Engineering to Medical Devices	February 3, 2016	Guidance for Industry and Food and Drug Administration Staff

List of Highest Priority Devices for Human Factors Review	February 3, 2016	Draft Guidance for Industry and Food and Drug Administration Staff

Summary:
Based on the clinical performance as documented in the pivotal clinical study, the MATCH IT! Antibody software v1.5 was found to have a safety and effectiveness profile that is similar to the predicate device.

5.8 Conclusions

Based on the Verification activities and Cybersecurity Assessment results, the assessments and data demonstrate that the MATCH IT!® Antibody software does not present issues of safety and effectiveness.