Section 5.0 510(k) Summary – BK210572

5.1	**Owner/Manufacturer:**	Immucor GTI Diagnostics, Inc.
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	Date Prepared:	March 31, 2021
5.2	**Device Trade Name:**	MATCH IT!® Antibody Version 1.4
	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:	Traditional 510(k)
	Device Class:	Class II

5.3 Name of Device for Claiming Equivalence

HLA Fusion™ Software 4.4 (BK160017)

5.4 Description of Device

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 assure correctness.

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 opened 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 assure 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 and a user's manual.

5.5 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 assure correctness.

For *In Vitro* Diagnostic (IVD) Use.

5.6 Indications for Use

MATCH IT! Antibody software v1.4 is an optional accessory to the following LIFECODES antibody detection kits for use with Luminex:

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

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.

5.7 Substantial Equivalence

The MATCH IT!® Antibody software has been available as a CE marked software for use with products marketed by Immucor GTI Diagnostics, Inc. This version of software is being submitted to be usable on 32-bit and 64-bit computer systems as an IVD product for the US market. Complete Software Lifecycle Development Process has been applied for the MATCH IT!® Antibody software. Within this submission, the studies performed to verify the MATCH IT!® Antibody Software are being provided.

No alternate devices are applicable in the market for use in evaluation of the

LIFECODES® Antibody kit results. A similar software which is product specific and not for use with the LIFECODES® assays is manufactured by One Lambda, HLA Fusion™ Software.

The table below provides the comparison between the MATCH IT!® Antibody software v1.4 and the predicate device.

#	ELEMENT/ FEATURE	PREDICATE DEVICE	CANDIDATE DEVICE	Comments
1	Trade Name	HLA Fusion™ Software 4.4 (BK160017)	MATCH IT!® Antibody software v1.4	---
2	Manufacturer	One Lambda, Inc	Immucor GTI Diagnostics, Inc.	---
3	Intended Use	HLA Fusion Software is a companion to One Lambda's antibody screening products.	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 assure correctness.	No Difference
4	Indications for Use	One Lambda software products are designed to assist personnel experienced in HLA analysis by suggesting antibody screening results. However, results must be carefully reviewed by a person qualified in antibody screening to assure correctness. The software may be used to aid in suggesting results, but should not be used as the sole method for determining reportable results. The software is meant as a laboratory aid, not as a source of definitive results.	MATCH IT! ® Antibody software v1.4 is an optional accessory to the following LIFECODES 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	No Difference

			assignment would need to be validated by lab personal prior to use.	
5	Software Environment	HLA Fusion software is designed to work in a centralized database environment on a network, or in a standalone configuration on your computer.	Same	No Difference
6	Hardware and Software Minimum Requirements	Microsoft® Windows 7 or 10 (32 bit and 64 bit)	Microsoft® Windows 10 operating systems	No Difference
		Microsoft .NET Framework version 4.5.1	.NET Framework Version 4.6 (Included with software)	Upgraded Requirement
		Visual JSharp (version must match the .NET Framework version you are using)	N/A	Visual JSharp not required
		Microsoft SQL 2008 R2, Microsoft® SQL Express 2014 (also requires Microsoft .NET Framework Version 3.5 SP1)	Microsoft® SQL Server 2016 Express (Included with software)	Upgraded Requirement
		1 GHz Pentium processor or equivalent	2.33 GHz or faster 64-bit processor	Upgraded Requirement
		32-bit(x86) microprocessor		
		1 GB hard disk space	50 GB hard disk space	Upgraded Requirement
		4 GB RAM	8 GB RAM	Upgraded Requirement
		8-bit graphics adapter and display	DirectX 9 or later graphics card with WDDM 1.0 driver	Upgraded Requirement
		VGA display with minimum of 1280 x 960 resolution	XGA display with 1024 x 768	Upgraded Requirement
		A mouse or other Windows compatible point device	Same	No Difference
		A Windows compatible printer driver	Same	No Difference
7	Data Import Requirements	Import raw data from the LABScan 100 and LABScan 3D flow analyzer	Designed to import csv files created by the Luminex 100/200 and FLEXMAP 3D	LABScan is the One Lambda brand name for the Luminex

				instrument
		Luminex is running software versions xPONENT 4.0, xPONENT 4.2 or xPONENT 4.3.	Luminex is running software versions xPONENT 3.1, 4.2, or 4.3	Both cover the most recent xPONENT 4.2 and 4.3
		The data file name, (also known as a session ID) must be 40 characters or less in length and include the .csv file extension.	The batch name must be 30 characters or less in length.	Same intention
		The data is generated based on original, unmodified templates provided by One Lambda, Inc.	The data present in the csv file must be generated using an unmodified Luminex template that is provided by Immucor GTI Diagnostics.	Same intention – use of unmodified templates for the Luminex instrument.
8	Data Analysis	Analyze the raw data and review the results in graphical form.	Same	No Difference
		Adjust Cut-off values to clarify the results.	Same	No Difference
		Easily update product information	Same	No Difference
		Search for specific data	Same	No Difference
9	Reporting	Create standard reports	Same	No Difference
		Create custom reports	Same	No Difference
10	UDI	00814695022571	10888234500810	---

Similarities between the MATCH IT! ® Antibody Software v1.4 and One Lambda HLA Fusion Software

1. MATCH IT!® Antibody Software and HLA Fusion™ Software have similar intended use and indications for use.

2. MATCH IT!® Antibody Software and HLA Fusion™ utilize raw data from the Luminex instrument employing, same bead based Luminex Assay technology and similar assay steps.

3. MATCH IT!® Antibody Software and HLA Fusion™ Software work in the same software environment.

Differences between the MATCH IT! ® Antibody Software v1.4 and One Lambda HLA Fusion Software

The differences between the predicate device and the candidate device reflect differences in technology available for the predicate device at the time of submission. 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.

5.8 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).

5.8.1 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

Software Documentation	Requirement for Moderate Concern devices	Included Yes/No	Explanation
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	Applies to Verification and	Yes	NA

Software Documentation	Requirement for Moderate Concern devices	Included Yes/No	Explanation
Report	Validation Documentation.		

5.8.2 Studies supporting safety and effectiveness of the candidate device

MATCH IT!® Antibody Software v1.4 is being submitted to be usable on 32-bit and 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 which provide 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 16.0, Software.

5.8.3 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 v1.4. 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 v1.4. 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.

5.8.4 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

5.9 Conclusion:

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.