2.0 510(k) SUMMARY – MATCH IT! ® DNA Software Version 1.3

I.	**Owner/Manufacturer:**	Immucor GTI Diagnostics, Inc.
	Address:	20925 Crossroads Circle, Waukesha, WI 53186 USA
	Phone:	262.754.1009
	Fax:	262.754.1078
	Name of Submitter:	Julie Ewend [jewend@immucor.com]
	Date Prepared:	December 26, 2019
II.	**Device Trade Name:**	MATCH IT!® DNA Version 1.3
	Common Name:	MATCH IT! ® DNA Software
	Classification Name:	Test, Qualitative, For HLA, Non-Diagnostic
	Division:	CBER
	Review Panel:	Hematology
	Product Code:	MZI
	Classification:	Unclassified
	Submission Type:	Special 510(k)
	Device Class:	2

III. Name of Device for Claiming Equivalence

LIFECODES MATCH IT! ® DNA Software Version 1.2 (BK150343)

IV. Description of Device

MATCH IT! ® DNA Software Version 1.3 is an accessory to aid in the evaluation of test results from Immucor GTI Diagnostics, Inc.. LIFECODES® HLA-SSO 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® HLA-SSO Typing Kits are listed in the MATCH IT! ® DNA Software Quick Reference Guide.

The MATCH IT! ® DNA Software is designed to analyze the raw data from the Luminex Fluoroanalyzer when used with LIFECODES® HLA-SSO Typing Kits. The raw data is in csv file format and consists of MEDIAN Fluorescent Intensity (MFI) values for each bead in an assay. The relative signal (MFI) obtained with the probes/bead in the LIFECODES® HLA-SSO assay can be used to assign the probes/beads as having positive or negative reactivity. This in turn provides the information needed to determine the suggested alleles. The generated csv files can be opened and the data processed with the MATCH IT! ® DNA Software. The calculations and subsequent analysis performed by the software are outlined in the MATCH IT! ® DNA Software User's Manual and the Instructions for Use of the

LIFECODES® HLA-SSO Typing Kits.

The MATCH IT! ® DNA Software is intended to assist laboratory personnel by providing a list of suggested alleles.

The software consists of one installation disk and a User's Manual.

V. Intended Use

MATCH IT!® DNA Software is an accessory to aid in the evaluation of test results from Immucor GTI Diagnostics, Inc.. LIFECODES® HLA-SSO 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.

VI. Substantial Equivalence

The Intended Use for 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 this submission, the studies performed to verify the modifications made to the MATCH IT! ® DNA Software are being provided. The modification of the software being presented in this submission is the compilation and verification of a 64 bit version of MATCH IT! ® DNA Software. There were no design or functionality changes. All elements of the software Design History File (DHF) for the 32 bit version were used as possible and design outputs were created for the compiled 64 bit version.

- The proposed revision of the MATCH IT! ® DNA Software User Manual Instructions and a Quick Reference Guide are provided in the labeling section. The Quick Reference Guide is available to users to supplement the User Manual.
- The company name has changed from Immucor Transplant Diagnostics, Inc. to Immucor GTI Diagnostics, Inc..
- Clarification of the product name is being provided as MATCH IT!® DNA Software.

Further description of these items is provided in items 1-3 below.

1. **Summary of Similarities and Differences between the MATCH IT! ® DNA Software v1.2 and the MATCH IT! ® DNA Software v1.3.**

   Similarities between the MATCH IT!® DNA Software v1.2 and the MATCH IT!® DNA Software v1.3:

- The Intended Use has not changed between versions of the software.
- There are no design or functionality changes between versions of the software.
- There are no changes to the algorithm applied for the LIFECODES® HLA SSO Typing kits.

Differences between the MATCH IT! ® DNA Software v1.2 and the MATCH IT!® DNA Software v1.3:

The computer operating system has been updated as described in Table 1 below:

Table 1: LIFECODES MATCH IT! DNA SOFTWARE SYSTEM REQUIREMENTS

#	ELEMENT/ FEATURE	PREDICATE DEVICE	CANDIDATE DEVICE	Comments
1	Trade Name	MATCH IT! DNA Software v 1.2	MATCH IT! DNA software v 1.3	--
2	Manufacturer	Immucor GTI Diagnostics, Inc.	Same	--
3	Intended Use	LIFECODES MATCH IT! DNA Software is an accessory to aid in the evaluation of test results from Immucor GTI Diagnostics, Inc. LIFECODES HLA SSO kits for use with Luminex. Due to the complex nature of HLA Testing, qualified laboratory personnel must review any result to assure correctness.	MATCH IT! DNA Software is an accessory to aid in the evaluation of test results from Immucor GTI Diagnostics, Inc. LIFECODES HLA SSO kits for use with Luminex. Due to the complex nature of HLA Testing, qualified laboratory personnel must review any result to assure correctness.	Removal of LIFECODES from product name.
4	Indications for Use	LIFECODES MATCH IT! DNA software, version 1.2 is an optional accessory to CE marked LIFECODES	MATCH IT! DNA software, version 1.3 is an optional accessory to LIFECODES HLA SSO kits, for use with Luminex, as	Removal of LIFECODES from product name. Removal of CE marked. The CE marked

		HLA SSO kits, for use with Luminex, as referenced in MATCH IT! DNA Quick Reference Guide - LC1497IVD.	referenced in MATCH IT! DNA Quick Reference Guide - LC1497IVD.	version is being prepared as an independent version from this device.
4	Software Environment	The software is designed to work in a centralized database environment on a network, or in a standalone configuration on your computer.	Same	No Difference
5	Hardware and Software Minimum Requirements	Microsoft™ Windows XP SP3, Vista, or Windows 7 (32-64 bit version) operating Systems	Microsoft™ Windows 10 (64 bit version) operating system	Update to Windows 10
		Microsoft .NET Framework version 4.0 (Included with software)	Microsoft. NET Framework Version 4.6 (Included with software)	Update to version 4.6
		Microsoft™ SQL Express 2008 (Included with software) (Optional) Microsoft™ SQL Server 2008 for increased storage capacity	Microsoft™ SQL Express 2016 (Included with software) (Optional) Microsoft™ SQL Server 2016 for increased storage capacity	Update to 2016 versions of SQL Express and SQL Server
		Pentium® 4 or Core 2 Duo	2.33 GHz or faster 64-Bit processor	Updated without listing brand of processor
		32-bit(x86) microprocessor	64-Bit processor	Update to 64 Bit processor
		10 GB hard disk space	50 GB hard disk space	Added for increased capacity
		4 GB RAM	8 GB RAM	Added for increased capacity
		24-bit graphics adapter and display	DirectX 9 or later graphics card with WDDM 1.0 driver	Newer graphics available

		XGA display with 1024 x 768	XGA display with 1024 x 768 resolution	No Difference
		A mouse or other Windows compatible point device	Same	No Difference
		A Windows compatible printer driver	Same	No Difference
6	Data Import Requirements	Designed to import csv files created by the Luminex 2.3 and xPONENT software versions.	Designed to import csv files created by the Luminex xPONENT 4.3 software.	Expanded to newer version of Luminex xPONENT software
		The data file name, (also known as a session ID) must be 40 characters or less in length and include the .csv file extension.	Same	No Difference
		The data present in the csv file must be generated using an unmodified Luminex template that is provided by Immucor GTI Diagnostics, Inc.	Same.	No Difference
7	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
8	Reporting	Create standard reports	Same	No Difference
		Create custom reports	Same	No Difference
9	UDI	UDI assigned for v1.2 10888234400394	UDI assigned for v1.3 10888234500803	UDI required as configured

Similarities between the MATCH IT! ® DNA software versions 1.2 and 1.3

1. MATCH IT!® DNA Software v1.2 and 1.3 have the same intended use and indications for use with removal of LIFECODES from the product name.

2. MATCH IT!® DNA Software v1.2 and v1.3 utilize raw data from the Luminex 100/200 instrument employing, same bead based Luminex Assay technology and similar assay steps.

3. MATCH IT!® DNA Software v1.2 and v1.3 work in same software environment.

Differences between the MATCH IT!® DNA software versions 1.2 and 1.3

The differences between the predicate device and the candidate device reflect differences in technology available 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.

1. **Company name and location change**

   The company name has changed from Immucor Transplant Diagnostics, Inc. to Immucor GTI Diagnostics, Inc. due to closing of the Immucor Transplant Diagnostics, Inc. facility. The device was transferred to the Immucor GTI Diagnostics, Inc. facility. This transfer was initiated April 2016 with completion through May 2017.

Current Name/Address	Prior Name/Address
Immucor GTI Diagnostics Inc.	Immucor Transplant Diagnostics, Inc.
20925 Crossroads Circle	550 West Avenue
Waukesha WI 53186 USA	Stamford CT 06902 USA

2. **Product name: MATCH IT!® DNA.**

   The software name is being defined as MATCH IT!® DNA. Previously, the Brand name of LIFECODES® was included when listing the product name in some instances. For consistency, the LIFECODES® brand will still apply but not be considered as part of the product name.

VII. Software-related Documentation

The following guidance documents issued by the agency have been referenced during preparation of this Special 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).

1. **Content of Pre-Market Submissions for Software Contained in Medical Devices.**

   As described in the guidance document "Guidance for the Content of Pre-Market Submissions for Software Contained in Medical Devices", for a Special 510(k), where modifications do not alter the intended use or the fundamental scientific technology of the device, only documentation related to the modification that prompted the submission is to be submitted. It is suggested to submit the regression testing performed to verify and validate the modifications including test plans, pass/fail criteria and a summarization of the results.

   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	Software design specification document.	Yes	NA

Software Documentation	Requirement for Moderate Concern devices	Included Yes/No	Explanation
(SDS)			
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

2. Studies supporting safety and effectiveness of the candidate device

The MATCH IT! ® DNA Software v1.3 project was to compile and verify a 64-bit version of the software. Unit testing as described below presents Verification and

Validation of the changes with the new software version. The Verification and Validation of the software modification is a part of the Functional, Scenario, UAT and Installation Testing.

Section 15.0, Performance Testing-Bench presents the Master Test Plan which defines the verification requirements which provide evidence that the MATCH IT!® DNA 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 18.0, Software.

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!® DNA Software v1.3. The following activities were performed:

- Identification of Threats and Risks
- Identification of Threat Agents (Threat Actors)
- Assessment of Impact and Likelihood of Threat Agent Actions
- Calculation of Risk

A Vulnerability Assessment report identified findings related to MATCH IT!® DNA Software. The level of risk associated with the findings were categorized as high, medium, low and informational. Applications already in place minimize concern with various identified findings to include Requirements for Passwords and Access at different User Levels, Secure System requirements (Service not exposed to public domains), and Network or Host firewall access restriction.

A Cybersecurity Guidance Document (MIDNA), has been prepared which will be provided to users describing steps to implement to reduce cybersecurity risks.

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!® DNA 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!® DNA software product cannot result in serious harm to the patient or user.
- MATCH IT!® DNA 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!® DNA 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

VIII. Conclusion:

Based on the Verification activities and CyberSecurity Assessment results, the assessments and data demonstrate that the modification to the MATCH IT!® DNA Software does not present new issues of safety and effectiveness.