510(k) Summary – MatchX software

In accordance with 21 CFR 807.87(h), a 510(k) summary is included that meets the conditions as outlined for a 510(k) summary in 21 CFR 807.92.

Submitter Information:

Owner/Manufacturer: Immucor GTI Diagnostics, Inc.
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Device:

Device Classification Name: Test, Qualitative, For HLA, Non-Diagnostic

Trade Name: MatchX (888628)

Common Name: MatchX Software

Review Panel: Hematology

Classification Product Code: MZI

Device Classification Regulation: N/A

Device Class: Class II

Predicate Devices

Predicate	Trade Name	Manufacturer	510(k) Number	Classification Product Code
MATCH IT! Antibody Software	MATCH IT! Antibody Software	Immucor GTI Diagnostics, Inc.	BK220762	MZI
MATCH IT! DNA Software	MATCH IT! DNA Software	Immucor GTI Diagnostics, Inc.	BK190439	MZI

Device Description Summary

MatchX Software is an accessory to aid in the evaluation of test results from Immucor GTI Diagnostics, Inc. LIFECODES® Antibody Detection kits and LIFECODES® HLA-SSO Typing kits for use with Luminex® instruments. Due to the complex nature of HLA Testing, qualified laboratory personnel must review any result to assure correctness.

Principles of the Procedure

The MatchX Software is designed to analyze the raw data coming from the Luminex Fluoroanalyzer when used with LIFECODES 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 for Antibody Detection kits or suggested alleles for HLA SSO Typing kits. The generated csv files can be opened and the data processed with the MatchX Software. The calculations and subsequent analysis performed by MatchX software are outlined in the Instructions for Use of the LIFECODES Kits.

The MatchX 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 MatchX software utilizes the analysis methodology set forth in the LIFECODES products Product Inserts.

LIFECODES Product	Product Insert Document Number
LIFECODES Class I ID	LC807IVD
LIFECODES Class II ID v2	
LIFECODES LifeScreen Deluxe	LC1003IVD
LIFECODES LifeScreen XP	LC1698IVD
LIFECODES LSA Class I	LC1683IVD
LIFECODES LSA Class II	
LIFECODES HLA-A eRES SSO Typing Kit	LC1436IVD
LIFECODES HLA-B eRES SSO Typing Kit	
LIFECODES HLA-C eRES SSO Typing Kit	
LIFECODES HLA-DRB1 eRES SSO Typing Kit	
LIFECODES HLA-DRB3,4,5 SSO Typing Kit	
LIFECODES HLA-DQA1/B1 SSO Typing Kit	
LIFECODES HLA-DPA1/B1 SSO Typing Kit	

Intended Use / Indications for Use:

MatchX Software is an accessory to aid in the evaluation of test results from Immucor GTI Diagnostics, Inc. LIFECODES® Antibody Detection kits and LIFECODES® HLA-SSO Typing kits for use with Luminex® instruments. Due to the complex nature of HLA Testing, qualified laboratory personnel must review any result to assure correctness.

MatchX is an optional accessory to the following LIFECODES Antibody detection kits and LIFECODES HLA-SSO Typing Kit for use with Luminex:

LIFECODES® LifeScreen Deluxe	(PN 628215)
LIFECODES® LifeScreen XP	(PN 628220)
LIFECODES® Class I ID	(PN 628200)
LIFECODES® Class II ID v2	(PN 628223)
LIFECODES® LSA Class I	(PN 265100IVD)
LIFECODES® LSA Class II	(PN 265200IVD)
LIFECODES® HLA-A eRES SSO Typing Kit	(PN 628913)
LIFECODES® HLA-B eRES SSO Typing Kit	(PN 628917)
LIFECODES® HLA-C eRES SSO Typing Kit	(PN 628921)
LIFECODES® HLA-DRB1 eRES SSO Typing Kit	(PN 628925)
LIFECODES® HLA-DRB 345 SSO Typing Kit	(PN 628927)
LIFECODES® HLA-DQA1/B1 SSO Typing Kit	(PN 628930)
LIFECODES® HLA-DPA1/B1 SSO Typing Kit	(PN 628936)

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 (IVD) Use.

Non-Clinical / Clinical Trials

Independent non-clinical / 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 and LIFECODES HLA-SSO assays. User Acceptance Testing has also been completed. The software meets the provisions of the standard IEC 62304, Software Life-cycle Processes.

Summary of Safety and Effectiveness

The MatchX software was developed in accordance with relevant regulations. The software was thoroughly tested, including Functional, Scenario, UAT, Installation Testing and Cybersecurity to ensure it was adequately developed and functioned according to its intended use. Based on the Verification activities and Cybersecurity Assessment results, the assessments and data demonstrate that the MatchX software does not present issues of safety and effectiveness.