

510(K) Summary

The assigned 510(k) number: BK150343

Submitted by

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Trade Name: MATCH IT!™ DNA Software v 1.2

Common Name: MATCH IT!™ DNA Software

Classification Name: Class II

Predicate Device: HLA Fusion™ Software, Version 3.0

510(k) Number: BK120014

Common Name: HLA Fusion™ Software

Trade Name: HLA Fusion™ Software

Intended Use: MATCH IT!™ DNA Software is an accessory to aid in the evaluation of test results from Immucor Transplant Diagnostics 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.

Description of the Device

The MATCH IT!™ DNA Software is designed to analyze the raw data coming from the Luminex Fluoroanalyzer when used with LIFECODES HLA SSO Typing 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 assay, can be used to assign the probes/bead 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 or any common spreadsheet programs such as Microsoft Excel or similar software. The calculations and subsequent analysis performed by the software are outlined in the MATCH IT!™ DNA Software User's manual and the Product Insert of the LIFECODES HLA SSO Typing Kits.

The MATCH IT!™ DNA Software is intended to assist qualified laboratory personnel by providing a list of suggested alleles. 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 disk and a user's manual.

Technological characteristics - Predicate and Candidate

MATCH IT!™ DNA Software v 1.2 (Candidate) and HLA Fusion™ Software similarities:

1. MATCH IT!™ DNA Software and HLA Fusion™ Software have similar intended use and indications for use.
2. MATCH IT!™ DNA Software and HLA Fusion™ Software 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 and HLA Fusion™ Software work in same software environment.

Support of Substantial Equivalence with Performance Data

#	ELEMENT/FEATURE	PREDICATE DEVICE	CANDIDATE DEVICE	Comments
1	Trade Name	HLA Fusion™ Software 3.0 (BK120014)	MATCH IT!™ DNA Software v 1.2	--
2	Manufacturer	One Lambda, Inc	Immucor Transplant Diagnostics, Inc	--
3	Indications for Use/Intended Use	All One Lambda software products are designed to assist personnel experienced in HLA analysis by suggesting typing results. However, any clinical or diagnostic results must be carefully reviewed by a person qualified in HLA typing 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.	LIFECODES MATCH IT!™ DNA Software is an accessory to aid in the evaluation of test results from Immucor Transplant Diagnostics 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.	No Difference
4	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

5	Hardware and Software Minimum Requirements	Microsoft Windows XP (minimum Service Pack 2 or 3) or Windows 7 (32 bit and 64 bit)	Microsoft™ Windows XP SP3, Vista, or Windows 7 (32-64 bit version) operating Systems	No Difference*
		Microsoft .NET Framework version 3.5 (Service Pack 1)	Microsoft. NET Framework Version 4.0 (Included with software)	Equivalent*
		Visual JSharp (version must match the .NET Framework version you are using)	N/A	Visual JSharp not required
		Microsoft SQL Express 2005 SP3, Microsoft SQL 2005 SP3, or SQL Server 2008 Express or Microsoft SQL Server 2008	Microsoft™ SQL Express 2008 (Included with software) (Optional) Microsoft™ SQL Server 2008 for increased storage capacity	No Difference*
		1 GHz Pentium processor or equivalent	Pentium® 4 or Core 2 Duo	Equivalent*
		32-bit(x86) microprocessor	Same	No Difference
		1 GB hard disk space	10 GB hard disk space	Equivalent*
		512MB RAM	4 GB RAM	Equivalent*
		8-bit graphics adapter and display	24-bit graphics adapter and display	Equivalent*
		VGA display with minimum of 1280 x 960 resolution	XGA display with 1024 x 768	Equivalent*
		A mouse or other Windows compatible point device	Same	No Difference
		A Windows compatible printer driver	Same	No Difference
6	Data Import Requirements	Import raw data from the LABScan 100 flow analyzer	Designed to import csv files created by the Luminex 2.3 and xPONENT software versions.	LABScan is the One Lambda brand name for the Luminex instrument
		Luminex is running software versions 1.7, 2.2, 2.3 or xPONENT 3.1	Luminex is running software versions 2.2, 2.3 or xPONENT 3.1	1.7 is not supported by MATCH IT!™ DNA v1.2
		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 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 Transplant Diagnostics.	Same intention – use of unmodified templates for the Luminex instrument.
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

**The differences between the predicate device and the candidate device reflect differences in technology that was available for the predicate 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.*

Studies supporting safety and effectiveness of the candidate device:

Accuracy Validation:

This study validates that MATCH IT!™ DNA v1.2 software is capable of utilizing EXP files and raw data CSV files and then generating matching typing results to 100% typing concordance to well characterized UCLA reference samples. Eight different LIFECODES HLA-SSO Typing Kits were used and their data was then analyzed in MATCH IT!™ DNA v1.2. For all eight typing kits each achieved a typing concordance of 100% and failures were at 0%, these results met the expected specifications for this study.

Locus	Typing Concordance	Failure
HLA-A	55/55 = 100%	0/55 = 0%
HLA-AeRES	54/54 = 100%	0/54 = 0%
HLA-B	67/67 = 100%	0/67 = 0%
HLA-BeRES	67/67 = 100%	0/67 = 0%
HLA-CeRES	70/70 = 100%	0/70 = 0%
HLA-DRB1	59/59 = 100%	0/59 = 0%
HLA-DRB1eRES	60/60 = 100%	0/60 = 0%
HLA-DRB345	65/65 = 100%	0/65 = 0%
Total	497/497 = 100%	0/497 = 0%

Conclusion

Based on comparison, MATCH IT!™ DNA v1.2 software is substantially equivalent to the predicate device. The performance evaluation studies support the safety and effectiveness of the device.