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## 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR 807.92.

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**Device Name:** HLA Fusion™ Software Version 4.0

**Product Code:** MZI

**Regulation Number:** 864.9175

**Type:** 510(k) Traditional  
BK160017

**Predicate Device:** HLA Fusion™ Software Version 3.0 (BK120014)

**Device Description:** HLA Fusion™ software is an accessory for the evaluation of One Lambda, Inc. products for typing and antibody detection. The software is to be used by qualified and trained personnel. HLA Fusion™ is to be used as a tool. The user is required to review, select, and accept all results as the final assignment.

HLA Fusion™ has six (6) primary functional components: navigation, analysis, reporter, record management, product management, and data storage.

HLA Fusion™ key features:

- Graphical representation of results.
- Graphical adjustments of cut-off values.
- Modular updates of test specifications into the system.

HLA Fusion™ Software merges the support of different technologies into a single software analysis tool. HLA Fusion™ processes the different raw data formats from each of the supported technologies into a reaction pattern based on positive and negative reaction values. HLA Fusion™ applies a common algorithm for either typing or antibody detection tests.

The significant change for HLA Fusion™ Software Version 3.0 to Version 4.0 is the addition of the LABType™ XR and CWD Typing Test products. This 510(k) submission focuses testing regarding the change to the software as result of this product addition.

**Accessories;**

HLA Fusion™ Software (BK070070 and BK120014) is a companion to the following One Lambda's molecular typing and antibody screening products:

- LABScreen™ Products (BK030069) for use with the LABScan™ 100 (Luminex® 100/200 instrument - BK073506) Flow Analyzer.
- LABScreen™ (BK130009) for use with LABScan3D™ (Luminex® FLEXMAP 3D® - instrument system (BK121399)
- LABScreen™ Multi (BK080071 and BK140141)
- LABType™ SSO DNA Typing Tests (BK120024) for use with LABScan3D™ (Luminex® FLEXMAP 3D® - instrument system (BK121399)
- LABType™ SSO Typing Test (BK020055)
- LABType™ XR and CWD DNA Typing Test (BK # pending)
- Lambda Antigen Trays (BK960011)
- Lambda Cell Tray (BK840013)
- FlowPRA™ (BK980015)
- Micro SSP™ HLA DNA Typing Test (BK960062)

**Indications for Use:**

HLA Fusion™ Software is an accessory for the evaluation of test results from One Lambda, Inc. products for molecular typing and antibody detection.

**Testing:**

Verification, Validation, and Testing demonstrate that the software performs as intended and it is safe and effective. The clinical testing conducted was for LABType XR and CWD DNA Typing Test products. No other product analysis algorithms changed therefore the analysis

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functions for other products were not tested for this submission.

**Conclusion:**

Based on the assessment of testing performed, One Lambda, Incorporated concludes that the HLA Fusion™ Software Version 4.0 is substantially equivalent to HLA Fusion™ Software Version 3.0 predicate device (BK120014).

**HLA Fusion™ Software Version 4.0  
Comparison to Predicate Device**

	<b>Predicate Device</b>	<b>Substantially Equivalent Device</b>
	<b>HLA Fusion™ Software Version 3.0</b>	<b>HLA Fusion™ Software Version 4.0</b>
<b>FDA Device Classification</b>	<b>BK120014</b> Unclassified,(CBER) Device Code MMH	<b>Unassigned #160017</b> Unclassified MZI
<b>Instrumentation</b>	LABScan™ 100 (Luminex® 100/200) instrument (BK073506), LABScan3D™ (Luminex® FLEXMAP 3D®) instrument system (BK121399), Elisa Reader	LABScan™ 100 (Luminex® 100/200) instrument (BK073506), LABScan3D™ (Luminex® FLEXMAP 3D®) instrument system (BK121399), Elisa Reader
<b>Intended Use</b>	Accessory for the evaluation of test results from One Lambda Inc. products for typing and antibodies detection	
<b>Standards Met</b>	Standards set by ASHI (American Society of Histocompatibility and Immunogenetics) for certification of clinical HLA laboratories.	
<b>Where Used and Target Population</b>	Preliminary clinical testing for recipients of bone marrow, tissue, or organ transplants. Test results should not be the only or final basis for a therapeutic decision. <sup>1</sup>	
<b>Software Requirements</b>	<ul style="list-style-type: none"> <li>• Microsoft® Windows® 7 (32 bit and 64 bit)</li> <li>• Microsoft® Windows® XP (minimum Service Pack 2 or 3) (32 bit)</li> <li>• For Windows XP systems, Microsoft Windows Installer 3.1</li> <li>• Microsoft.NET Framework Version 3.5 (Service Pack 1)</li> <li>• Visual JSharp (version must match the .NET Framework version you are using)*</li> <li>• Microsoft SQL Express 2005 SP 3, Microsoft SQL Server 2005 SP 3, or SQL Server 2008 Express or Microsoft SQL Server 2008</li> </ul>	<ul style="list-style-type: none"> <li>• Microsoft® Windows 7 or Microsoft® Windows 8.1 (32 bit or 64 bit)</li> <li>• Microsoft® .NET Framework Version 4.5.1</li> <li>• Visual JSharp (version must match the .NET Framework version you are using)</li> <li>• Microsoft SQL 2008 R2, Microsoft® SQL Express 2014 (also requires Microsoft .NET Framework Version 3.5 SP1)</li> <li>• Microsoft .NET Framework Version 3.5 SP1 is not included with HLA Fusion software distribution</li> </ul>

	<b>Predicate Device</b>	<b>Substantially Equivalent Device</b>
	<b>HLA Fusion™ Software Version 3.0</b>	<b>HLA Fusion™ Software Version 4.0</b>
<b>Hardware Requirements</b>	<ul style="list-style-type: none"> <li>• 1 GHz Pentium Processor</li> <li>• 32-bit (x86) microprocessor</li> <li>• 1 GB hard disk space (more may be required for large databases)</li> <li>• 512MB RAM</li> <li>• 8-bit graphics adapter and display (for 256 simultaneous colors)</li> <li>• VGA display with minimum of 1280 x 960 resolution</li> <li>• A mouse, or another Windows® compatible pointing device; mouse with wheel required for certain products.</li> <li>• A Windows® compatible printer driver (PDF Distiller, or the Microsoft Document Image Writer are available for free)</li> </ul>	<ul style="list-style-type: none"> <li>• M1 GHz Pentium Processor</li> <li>• 32-bit (x86) microprocessor</li> <li>• 1 GB hard disk space (more may be required for large databases)</li> <li>• 512MB RAM</li> <li>• 8-bit graphics adapter and display (for 256 simultaneous colors)</li> <li>• VGA display with minimum of 1280 x 960 resolution</li> <li>• A mouse or another Windows® compatible pointing device; mouse with wheel required for certain products</li> <li>• A Windows® compatible printer driver (PDF Distiller, or the Microsoft Document Image Writer are available for free)</li> </ul>
<b>Programming Language</b>	C#. NET (Developed on Microsoft.NET Framework Version 3.5 SP1)	C#. NET (Developed on Microsoft.NET Framework Version 4.5.1)
<b>Databases</b>	Microsoft® SQL Server 2005 & Microsoft® SQL Server 2008 R2	Microsoft® SQL Server 2008 R2 & Microsoft® SQL Server Express 2014
<b>Main Components</b>	Application software and database file.	
<b>Data Format</b>	Bead fluorescence and count from CSV file, Manual input.	
<b>Evaluation of Results</b>	Reaction Pattern Matching, Epitope Analysis, and Tail Analysis	
<b>Performance Features</b>	Point and click data entry	
	Performs research based on sample ID and patient ID of saved screening results.	
	Determines typing and antibody analysis of test results by interactive graphical tools.	
	Actual assignments made by user.	
	Use with One Lambda, Inc. typing and antibody screening products.	
	Graphical and interactive display for the analysis.	
	Generates and prints reports	

<sup>1</sup>A final leukocyte cross match test is needed to rule out specific allo-sensitization to the potential donor organ including the possible presence of pre-formed antibodies against either HLA or non-HLA antigens that could cause acute graft rejection.

### Conclusion:

HLA Fusion™ Software 4.0 is substantially equivalent to the predicate device HLA Fusion™ Software 3.0 (BK120014) because both are tools used in the preliminary clinical testing for recipients on bone marrow, tissue, or organ transplants, both use the same evaluation for results, and both are softwares that are combined with One Lambda, Incorporated HLA products.