

510K Summary

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

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Device Name: HLA Fusion™ Software, Version 3.0

Classification/
Device Code: Unclassified, MZI

Predicate Device: HLA Fusion™ Software, Version 1.0, BK070070

Device Descriptions: 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 6 primary functional components – navigation, analysis, reporter, record management, product management and data storage.

HLA Fusion™ key features:

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

HLA Fusion™ 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 test.

HLA Fusion™ uses a MS SQL Server.

HLA Fusion™ shall be run on Windows® 7 and Windows® XP.

HLA Fusion™ was developed in C# .NET.

Indications for Use: HLA Fusion Software is an accessory for the evaluation of test results from One Lambda Incorporated products for typing and antibodies detection

Testing: Verification, Validation and Testing demonstrate that the software performs as intended and is safe and effective.

Conclusion: Based on the assessment of testing performed, One Lambda Incorporated concludes that the HLA Fusion™ Software is substantially equivalent to HLA Visual™ Software predicate device.