



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

One Lambda, Incorporated
Attention: Mr. Don Arii
21001 Kittridge Street
Canoga Park, CA 91303

Re: BK120014

Trade/Device Name: HLA Fusion™ Software, Version 3.0
Regulatory Class: Unclassified
Product Code: MZI
Dated: December 7, 2012
Received: December 13, 2012

Dear Mr. Arii:

This letter corrects our substantially equivalent letter of December 18, 2012. The product code has been changed to MZI.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, continue to market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice on promotional labeling and advertisement for your device, please contact CBER's Advertising and Promotional Labeling Staff at CBERAPLB@fda.hhs.gov. If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact CDRH's Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

You may obtain other general information on your responsibilities under the Act from CDRH's Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

If you have any minor clarification questions concerning the contents of the letter, please contact Cherry Geronimo at (240) 402-9555 or cherry.geronimo@fda.hhs.gov.

Sincerely,

Jay S. Epstein, MD
Director
Office of Blood Research and Review
Center for Biologics Evaluation and Research

Enclosure: IFU Statement

Indications for Use

510(k) Number: BK120014

Device Name: HLA Fusion™ Software, Version 3.0

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.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CBER, Office of Blood Research and Review

Division Sign-Off, Office of Blood Research and Review