



**GRANT – DE NOVO  
November 28, 2022**

One Lambda Inc.  
Attention: Angela Estany  
22801 Roscoe Boulevard  
West Hills, CA 91304

Re: BR220737

Trade/Device Name: SeCore™ CDx HLA Sequencing System  
Regulation Number: 21 CFR 866.5960  
Regulation Name: Human Leukocyte Antigen Typing Companion Diagnostic Test  
Regulatory Class: Class II  
Product Code: QUK  
Dated: June 27, 2022  
Received: July 1, 2022

Dear Angela Estany:

The Center for Biologics Evaluation and Research (CBER) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the SeCore™ CDx HLA Sequencing System, a prescription device under 21 CFR Part 801.109 with the following indications for use:

The SeCore CDx HLA Sequencing System is intended for the detection of human leukocyte antigen A-locus (HLA-A) alleles using genomic DNA isolated from whole blood samples. The device is intended to be used as a companion diagnostic (CDx) to aid in the selection of HLA-A\*02:01 positive patients with unresectable or metastatic uveal melanoma who may benefit from treatment with KIMMTRAK® (tebentafusp-tebn) when used in accordance with approved therapeutic labeling.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact [CBERProductJurisdiction@fda.hhs.gov](mailto:CBERProductJurisdiction@fda.hhs.gov). FDA concludes that this device should be classified into Class II. This order, therefore, classifies the SeCore™ CDx HLA Sequencing System, and substantially equivalent devices of this generic type, into Class II under the generic name Human Leukocyte Antigen Typing Companion Diagnostic Test.

FDA identifies this generic type of device as:

**Human Leukocyte Antigen Typing Companion Diagnostic Test.** A human leukocyte antigen (HLA) typing companion diagnostic (CDx) test is a prescription

genotyping or phenotyping in vitro diagnostic product intended for use as an aid in identifying patients who have specific HLA allele(s) or express specific HLA antigen(s) and may benefit from treatment with a corresponding therapeutic product or are likely to be at increased risk for serious adverse reactions as a result of treatment with a corresponding therapeutic product.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On July 1, 2022, FDA received your De Novo requesting classification of the SeCore™ CDx HLA Sequencing System. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the SeCore™ CDx HLA Sequencing System into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request FDA has determined that, for the previously stated indications for use, the SeCore™ CDx HLA Sequencing System can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Identified Risks	Mitigation Measures
Inaccurate test results (false positive or false negative results) can result in adverse health consequences	General controls and special controls (1), (2), (3), (4)
Failure of software to correctly interpret test results can result in adverse health consequences	General controls and special control (2)(viii)

In combination with the general controls of the FD&C Act, the Human Leukocyte Antigen Typing Companion Diagnostic Test is subject to the following special controls:

- (1) The intended use of the device must specify the target HLA allele(s) or antigen(s), the patient population(s), and the corresponding therapeutic product(s).
- (2) Design verification and validation must include:

- (i) Detailed documentation of an analytical accuracy study that uses well-characterized samples including clinical samples from intended use population(s) focusing on the target allele(s) needed for patient selection;
- (ii) Detailed documentation of precision studies (repeatability, reproducibility) that evaluate possible sources of variation that may affect test results;
- (iii) Detailed documentation of a study determining range of input sample concentrations that meet performance specifications;
- (iv) Detailed description of the ambiguity resolution method, if applicable;
- (v) For a sequencing-based assay, documentation of coverage and predefined coverage threshold of target genomic regions, pertinent variant types, and sequence contexts;
- (vi) For multiplex assays, documentation of a risk assessment and design specifications that are in place to prevent incorrect reactivity assignment;
- (vii) Description of a plan on how to ensure the performance of the device does not change when new HLA alleles are identified, and/or when reactivity assignments are changed; and
- (viii) Detailed description of device software including standalone software, or software and bioinformatics analysis pipeline, if applicable, incorporated in the instruments, and documentation of software including the level of concern and associated risks, software requirement specifications, software design specifications (e.g., algorithms, alarms and device limitations), hazard analysis, traceability matrix, verification and validation testing, unresolved anomalies, hardware requirements, and effective cybersecurity management.

(3) Clinical validity data demonstrating the following, as applicable:

- (i) Which patients identified by the HLA CDx test are most likely to benefit from the corresponding therapeutic product;
- (ii) Which patients identified by the HLA CDx test are likely to be at increased risk for serious adverse reactions as a result of treatment with the corresponding therapeutic product.

Data may include summary reports from clinical trials, comparison studies using clinical samples, or through an alternative approach determined to be appropriate by FDA.

(4) If the HLA test used in the clinical trials is different from the HLA CDx test in the premarket notification submission, the submission must include results of a bridging study, or an alternative approach determined to be appropriate by FDA.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the Human Leukocyte Antigen Typing Companion Diagnostic Test they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD & C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

If you have any questions concerning the contents of the letter, please contact Courtney White at (301) 796-0636 or by email at [courtney.white@fda.hhs.gov](mailto:courtney.white@fda.hhs.gov).

Sincerely,

Orieji Illoh, MD  
Director  
Division of Blood Components and Devices  
Office of Blood Research and Review  
Center for Biologics Evaluation and Research