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:	LABType™ XR and CWD DNA Typing Test
Classification/ Product Code:	Unclassified / MZI
Classification Name:	Test, Qualitative, for HLA, Non-Diagnostic
Predicate Device:	LABType® SSO DNA Typing Tests For Use With LABScan™ 3D (BK120024)
Device Description:	LABType™ XR and CWD DNA C-Locus Class I Typing Test is the addition of C-Locus to LABType™ XR and CWD DNA Typing Test (BK160018 clearance for A, B, and DRB1 loci). LABType™ XR and CWD DNA Typing Test target HLA Class I A, B and C-locus and HLA Class II DRB1-locus, and also contains probes that will type for Common Well Documented HLA alleles based on the current CWD catalog available on the IMGT/HLA database. The typing test products are used in conjunction with the LABScan3D™ instrument (Luminex® FLEXMap 3D® instrument). The typing tests apply Luminex technology to the reverse SSO DNA typing method. The LABScan3D™ instrument combines dyed fluorescent microsphere sets to allow multiplexing of up to 500 unique assays within a single sample. In this assay, target DNA is PCR-amplified using a group specific primer. The Polymerase Chain Reaction (PCR) product is biotinylated, which allows it to be detected using R-Phycoerythrin-conjugated streptavidin (SAPE). The PCR

product is denatured and allowed to rehybridize to complementary DNA probes conjugated to fluorescently coded microspheres. A bench-top analyzer (LABScan3D™) identifies the fluorescent intensity of Phycoerythrin (PE) on each microsphere. Positive reactions are identified by comparing the fluorescent signal for each test probe as a percent of positive internal control probe signal to a given cut-off value.

Separately available analysis software (HLA Fusion™) can be used to assist in determining HLA typing.

Operational Principles:

HLA antigens are polymorphic heterodimers encoded by genes located on the short arm of chromosome 6 and regulate the immune response to pathogens and distinguish "self" from "non-self" in transplantation immunology. Histocompatibility testing allows the matching of organ recipients and donors with the degree of matching accuracy impacting the clinical outcome of organ and bone marrow transplantation. Molecular-based typing methods have been refined for practical testing in the clinical lab setting. LABType™ XR and CWD DNA Typing Test uses sequence-specific oligonucleotide probes (SSO) bound to fluorescently coded microspheres to identify alleles encoded by the sample DNA. The introduction of a step to amplify the target DNA by polymerase chain reaction (PCR), coupled with hybridization and detection in a single tube, makes this method suitable for large-scale testing.

Accessories:

HLA Fusion Software Version 4.0 (BK160017)
LABScan3D™ [Luminex® FLEXMAP 3D® - instrument system (K121399)]

Intended Use:

For use to determine HLA A, B, C and DRB1 locus typing to aid in transfusion and transplantation donor recipient matching.

Table 1. Device Comparison Table

	Predicate Device	Substantially Equivalent Device
	LABType® SSO DNA Typing Tests For Use With LABScan 3D	**LABType™ XR and CWD DNA Typing Test (C-Locus)**
FDA Device Classification	BK120024 Unclassified under CBER Device code - MZI	BK170053 New Device Unclassified/MZI
Intended Use	DNA typing of HLA Class I or Class II alleles	For use to determine HLA A, B, C and DRB1 locus typing to aid in transfusion and transplantation donor recipient matching.
Clinical Usage	Molecular typing of HLA using Luminex technology	
Standards Met	Standards set by ASHI (American Society of Histocompatibility and Immunogenetics) for certification of clinical HLA Laboratories	
Where Used and Target population	Preliminary clinical testing for identification (and potential matching) of HLA alleles for donors and recipients of bone marrow, tissue, or organ transplants.	
Assay Method	DNA typing (SSO)	
Reactive Ingredient	HLA Sequence-specific oligonucleotide probes	
Specimen Type	DNA	
Controls	Positive (HLA gene PCR amplicon, binding to a universal probe) and Negative (non-HLA gene PCR amplicon, no binding to probes)	
Detection Reagents	Streptavidin-PE (PE = R-Phycoerythrin)	
Software Technology	HLA Fusion™ Software Version 3.0 (BK120014)	HLA Fusion™ Software Version 4.0 (BK160017)
Instrumentation	LABScan3D™ (Luminex® FLEXMAP 3D®) instrument system (K121399)	
Positive Reaction	Fluorescent signal due to binding of specific DNA probes	
Evaluation of Results (HLA genotyping is based on published information on HLA DNA sequences, or defined serological reagent specificity)	Assignment of specificity by matching the reaction pattern to the known sequence specificity of the probes included in the panel. Highly complex information needs to be reviewed by a certified HLA professional.	
Performance	Comparable sensitivity and specificity of typing results	

LABType™ XR and CWD DNA Typing Test (LABType™ XR Class I C Locus Typing Test and LABType CWD Class I C Locus Typing Test) is substantially equivalent to the predicate device LABType® SSO DNA Typing Tests for use with LABScan3D™ device using Luminex technology for molecular typing and is a tool used in preliminary clinical testing. No new safety or effectiveness issues were raised.

Clinical Testing:

Hoxworth Blood Center University of Cincinnati and City of Hope used the predicate device LABType® SSO DNA Typing Tests for Use with LABScan3D for comparative testing (BK120024). For comparative testing, UCLA School of Medicine used Next Generation Sequencing. The performance of the LABType™ XR Class I C Locus Typing Test and LABType CWD Class I C Locus Typing Test were verified and testing demonstrates safety and effectiveness (Table 2).

Table 2. Test Results Summary

Testing	**Agreement (HLA Typing)**
Verification	
Performance Evaluation	**LABScan3D™**
1 product lot of LABType™ XR Class I C Locus Typing Test and 1 product lot of LABType CWD Class I C Locus Typing Test tested with two sets of 95 approved reference samples	
- Concordance	100% where one pair of the reported alleles is the same as the typing results of the reference sample.
Detection Limits	**LABScan3D™**
LABType CWD Class I C Locus Typing Test and LABType XR Class I C Locus Typing lots tested with 8 reference samples at 3 concentrations: 40, 20 and 10 ng/µL (24 reference samples total)	
- Concordance	100%
Robustness	**LABScan3D™**
1 product lot of LABType™ XR Class I C Locus Typing Test and 1 product lot of LABType CWD Class I C Locus Typing Test tested with two sets of 95 approved reference samples (samples selected for HLA Class I and II genes with maximum diversification of HLA typing to test as much specificity as possible) at both 50% concentration and 100% concentration of microspheres	
- Concordance	100%
Lot-to-Lot Consistency	**LABScan3D™**
3 product lots of LABType™ CWD Class I C Locus Typing Test and 3 product lots of LABType XR Class I C Locus Typing tested with 32 approved reference samples in triplicate per lot. Each lot tested on different days. 1 technician, 1 lot x 32 samples in triplicate x 3 runs	
- Concordance	100%
Reproducibility	**3 Technicians / 1 LABScan3D™ device**
1 product lot of LABType™ CWD Class I C Locus Typing Test and 1 product lot of LABType XR Class I C Locus Typing Test tested with 16 reference samples 3 technicians in 2 separate runs/day on 5 non-consecutive days within a 20-day period	
- Concordance	100%
Clinical Testing – 3 sites	
Performance Evaluation	**LABScan3D™**
2 product lot of LABType™ XR Class I C Locus Typing Test and 2 product lots of LABType CWD Class I C Locus DNA Typing Test tested with 32 samples per lot DNA concentrations of 20ng/µL	
- Concordance:	100%
Reproducibility	**3 technicians/LABScan3D™**
1 product lot of LABType™ XR Class I C Locus Typing Test 16 samples in duplicate twice per day (64 samples tested per day) over 5 non-consecutive days within a 20 day period and 1 product lot of LABType CWD Class I C Locus Typing Test 16 samples in duplicate twice per day (64 samples tested per day) over 5 non-consecutive days within a 20 day period	
- Concordance:	100%

Bead Counts	Expected >100 beads per region
All of the above experiments (in-house and clinical testing)	
- Observed	>100

Overall Conclusion:

Extensive data generated from in-house and clinical testing demonstrates that LABType™ XR and CWD DNA Typing Test (LABType™ XR Class I C Locus Typing Test and LABType CWD Class I C Locus Typing Test) for use with the LABScan3D™ is safe and effective. Submitted information is complete and supports that LABType™ XR and CWD DNA Typing Test (LABType™ XR Class I C Locus Typing Test and LABType CWD Class I C Locus Typing Test) is substantially equivalent to LABType® SSO DNA Typing Tests for use with LABScan3D™.