510(K) Summary

The assigned 510(k) number: BK150302

Submitted by

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Trade Name: LIFECODES HLA-DQA1/B1 SSO Typing Kit
LIFECODES HLA-DPA1/B1 SSO Typing Kit

Common Name: LIFECODES HLA-SSO Typing Kits for use with Luminex

Classification Name: unclassified

Product Code: MZI, Test, Qualitative, for HLA, Non-Diagnostic

Predicate Device: LABType SSO Class II DQA1 and DQB1 Typing Test
LABType SSO Class II DPA1 and DPB1 Typing Test

510(k) Number: BK120024
Common Name: LABType ® SSO DNA Typing Tests for use with LABScan™3D
Trade Name: LABType SSO Class II DQA1 and DQB1 Typing Test
LABType SSO Class II DPA1 and DPB1 Typing Test

Intended Use: DNA Typing of Class I or Class II HLA alleles to aid in transfusion and transplantation donor and recipient matching.

Indication for Use:
LIFECODES HLA-SSO Typing Kits are qualitative tests for the DNA typing of Class I and Class II HLA alleles, to aid in transfusion and transplant donor and recipient matching. The source of material tested is DNA. The products are used by trained professionals in medical settings. No component of the kit comes in direct contact with the patient. Potential donor/recipient DNA typing are not the sole tests upon which a clinical decision affecting the patient is based; a cross-match is routinely required prior to making a decision to transplant. These kits are intended for In Vitro Diagnostic (IVD) use.

Description of the Device
The LIFECODES HLA-SSO Typing Kits are used to determine an individual’s HLA type. The kits are analyzed on the Luminex platform (Luminex LX100/200 Instrument; K073506). Sequence-specific oligonucleotides (SSOs), bound to microspheres (with unique fluorescent signatures), to identify the HLA alleles present in DNA samples. The device family consists of kits for typing the HLA-A, HLA-B, HLA-C, HLA-DP, HLA-DQ and HLA-DRB Loci.
DNA-based HLA-Typing using PCR amplified DNA is a common laboratory procedure. PCR amplification of DNA is used as the means to enrich for a selected DNA region. For HLA typing, a subsequent assay is utilized to determine the properties of amplified DNA. Several types of assays, such as SSP, direct SSOP, RFLP and reverse SSOP dot blot technologies, have been
used in HLA typing. LIFECODES HLA-SSO Typing kits utilize sequence-specific oligonucleotides (SSOs) to identify which HLA alleles are present in a PCR amplified sample.

**Technological characteristics - Predicate and Candidate**

**LIFECODES SSO Typing Kits (Candidate) and LABType SSO Class II Typing Test (Predicate) similarities:**

1. LIFECODES SSO Typing Kit and LABType SSO Class II Typing Test have the same intended use and indications for use.
2. LIFECODES SSO Typing kit and LABType SSO Class II Typing Test utilizes the same technology (a bead based Luminex Assay) and assay steps.
3. LIFECODES SSO Typing kit and LABType SSO Class II Typing Test uses the same sample type (DNA).

**LIFECODES SSO Typing Kits and LABType SSO Class II Typing Test differences:**

1. There are 5 steps in LABType SSO Class II Typing assay but only 4 steps in LIFECODES SSO Typing kit assay. LABType SSO Class II Typing assay includes a separate denaturation step to separate each single strand from double stranded DNA. In the LIFECODES SSO Typing Kits, amplification and denaturation occur in same step to generate single stranded DNA. The difference in the number of steps by which single stranded DNA is generated does not render the device Not Substantially Equivalent. This difference in steps does not mean any difference in safety or effectiveness of candidate device, when compared to predicate. The critical characteristic is that single stranded DNA is available for probe hybridization to occur. Additionally, the candidate device uses same technological characteristics of LIFECODES HLA SSO Typing Kit family of devices, already cleared.

2. The predicate device can be analyzed using LABScan3D™ and Luminex 100/200 instrument. The Candidate device uses Luminex 100/200 instrument.

**Support of Substantial Equivalence with Performance Data:**

<table>
<thead>
<tr>
<th>Clinical Comparison</th>
<th>Site 1</th>
<th>Site 2</th>
<th>Site 3</th>
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<tr>
<td>LABType SSO Class II Typing Test vs LIFECODES HLA SSO Typing Kits</td>
<td>HLA-DQA1/B1 : 100% Concordance (256/256)</td>
<td>HLA-DQA1/B1 : 100% Concordance (252/252)</td>
<td>HLA-DQA1/B1 : 99.61% Concordance (258/259)</td>
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<tr>
<td></td>
<td>HLA-DPA1/B1 : 100% Concordance (252/252)</td>
<td>HLA-DPA1/B1 : 99.61% Concordance (258/259)</td>
<td>HLA-DPA1/B1 : 100% Concordance (252/252)</td>
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**Studies supporting safety and effectiveness of the candidate device:**

**Accuracy**

The HLA-DQA1/B1 kit (Catalog # 628930) shows 99.2% agreement for DQA Alleles (96.2% lower boundary using one-sided exact method at 95% confidence interval) and 98.4% agreement for DQB Alleles (95.2% lower boundary using one-sided exact method at 95% confidence interval) when comparing HLA Typing results at 2 fields in 123 and 130 well characterized samples, respectively.
The HLA-DPA1/B1 kit (Catalog # 628936) shows 100% agreement for DPA Alleles (97.7% lower boundary using one-sided exact method at 95% confidence interval) and 98.5% agreement for DPB Alleles (95.4% lower boundary using one-sided exact method at 95% confidence interval) when comparing HLA typing results at 2 fields in 133 and 135 well characterized samples, respectively.

**Repeatability**

100% concordance was achieved with LIFECODES HLA-DPA1/B1 and LIFECODES HLA-DQA1/B1 SSO Typing kits in studies performed at 3 sites, two operators over the course of five non-consecutive days that spanned a total duration of twenty calendar days. Sample and assay testing was conducted in duplicate for each assay, resulting in ten assays performed by each Operator. Instrument to instrument repeatability was 100%.

**Reproducibility**

Study demonstrates that the reproducibility between 3 different lots of the LIFECODES HLA-DPA1/B1 SSO Typing Kit and LIFECODES HLA-DQA1/B1 SSO Typing Kit with 3 different operators is 100%.

**Stability / Shelf life**

Stability data supports the shelf life of at least 24 months for LIFECODES HLA-DPA1/B1 SSO Typing kits and 20 Months for LIFECODES HLA-DQA1/B1 SSO Typing kits

**Interfering Substances**

In laboratory testing, the following substances demonstrated some inhibition when evaluated with LIFECODES HLA-DQA1/B1 and LIFECODES HLA-DPA1/B1 SSO Typing Kits. The highest concentration of interfering substances without inhibition is Sodium Dodecyl Sulfate (0.005% (w/v)), Ethanol (500mM), Phenol (0.125% (v/v)), Sucrose (0.1M), EDTA (500 µM), ACD, (0.1% (v/v)), Cholesterol (1X), Bilirubin (16.4 µM), Hemoglobin (0.0156 mg/ml) and Hemolyzed Blood (0.1 % (v/v)).

**Conclusion**

Based on comparison, LIFECODES HLA-DPA1/B1 and LIFECODES HLA-DQA1/B1 SSO Typing kits are substantially equivalent to the predicate devices. The performance evaluation studies support that the devices do not present new issues of safety and effectiveness.