Section 5.0 510(k) Summary - BK210573 and BK210574

1. **Submitter**

Owner's Name:	Immucor GTI Diagnostics, Inc.
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2. **Name of Device**

Device Name:	LIFECODES® LSA™ Class I (BK210573) LIFECODES® LSA™ Class II (BK210574)
Classification:	Unclassified
Device Code:	MZI

3. **Name of Predicate Device for Claiming Equivalence**
   LABScreen Single Antigen HLA Class I Combi (BK030069)
   LABScreen Single Antigen HLA Class II Group 1 (BK130009)

4. **Description of Device**
   Human leukocyte antigens (HLA) are a system of glycoproteins that have a functional role in the presentation of peptides to the immune system. However, as a highly polymorphic system, HLA molecules can become the targets of antibody responses in people during pregnancy, transfusion of blood products, or organ transplant rejection. Generally, alloimmunization leads to the production of HLA antibodies in approximately 33% of exposed individuals. The presence or absence of these HLA-specific antibodies has a role in determining the survival of transplant allografts.

   LIFECODES LSA Class I Beads are designed to detect IgG antibodies to HLA Class I glycoproteins. LSA Class I is composed of different Luminex Beads to which purified recombinant Class I HLA glycoproteins are conjugated.

   LIFECODES LSA Class II Beads are designed to detect IgG antibodies to HLA Class II glycoproteins. LSA Class II is composed of different Luminex Beads to which purified recombinant Class II HLA glycoproteins are conjugated.

   Test Procedure
   An aliquot of the Beads is allowed to incubate with a small volume of test serum sample. The sensitized beads are then washed to remove unbound antibody. An anti-Human IgG antibody conjugated to phycoerythrin is then added. After another incubation, the test sample is diluted and analyzed on the Luminex instrument. The signal intensity from each bead is compared to the signal intensity of the lowest ranked locus-specific bead included in the bead preparation to determine if the bead is positive or negative for bound alloantibody.

5. Intended Use

LIFECODES LSA Class I is a bead-based immunoassay used to qualitatively detect HLA IgG antibodies to aid donor and recipient matching in transfusion or transplantation. Luminex Instrument and XY Platform are required to run the LIFECODES LSA Class I assay. The MATCH IT!® Antibody Software is intended as an aid in the analysis of LIFECODES LSA Class I assay.

LIFECODES LSA Class II is a bead-based immunoassay used to qualitatively detect HLA IgG antibodies to aid donor and recipient matching in transfusion or transplantation. Luminex Instrument and XY Platform are required to run the LIFECODES LSA Class II assay. The MATCH IT!® Antibody Software is intended as an aid in the analysis of LIFECODES LSA Class II assay.

6. Substantial Equivalence

All elements of the Design History File (DHF) for the proposed device were used as possible and design outputs were created for the proposed device.

Table 5-1 provides the comparison between LIFECODES LSA Class I and One Lambda LABScreen Single Antigen HLA Class I Combi.

Table 5-1

#	Features / Characteristics	Candidate Device	Predicate Device
1	Intended Use	LIFECODES LSA Class I is a bead-based immunoassay used to qualitatively detect HLA IgG antibodies to aid donor and recipient matching in transfusion or transplantation. Luminex Instrument and XY Platform are required to run the LIFECODES LSA Class I assay. The MATCH IT! Antibody Software is intended as an aid in the analysis of LIFECODES LSA Class I assay.	LABScreen products are intended for use in detection of HLA antibody using flow cytometric technology
2	Technology	Flow Cytometric Technology	Flow Cytometric Technology
3	Specimen Collection	Blood without anticoagulant (serum)	Serum or Plasma
4	Reportable Results	Qualitative assay; results are reported as positive or negative for each antigen present in the panel.	Assignment of antibody specificity by matching the reaction pattern to the known composition of the antigen panel
5	Packaging Configuration	24 Tests Kit	25 Test Kit
6	Reagents		
	LSA Class I Beads Mix	A blend of beads each conjugated with a different single Class I HLA glycoprotein plus control beads.	LABScreen™ Class I Single Antigen Bead Mix

	LSA Conjugate Concentrate	Goat anti-Human IgG conjugated to phycoerythrin in a phosphate-based storage buffer containing NaCl, Tween2- and sodium azide.	PE-conjugated 2nd Ab (anti-Human IgG)
	LIFECODES Wash Buffer	A phosphate-based buffer containing NACl, Tween-20, sodium azide and bovine serum albumin.	LABScreen Wash Buffer – 10X
	LSA Class I Positive Control	This serum or sera blend is obtained from individual(s) shown to be alloimmunized to HLA antigens and will react with most of the LSA Class I beads.	N/A
	LSA Class I Negative Control	This serum or sera blend is obtained from individual(s) known to have no antibodies to HLA antigens and will react with few if any of the LSA Class I beads.	Negative Control Serum (for HLA)
7	Instructions for Use (IFU)	LIFECODES LSA Class I and LIFECODES LSA Class II Product Insert	One Lambda LABScreen Product Insert

Table 5-2 provides the comparison between LIFECODES LSA Class II and One Lambda LABScreen Single Antigen HLA Class II Group 1.

Table 5-2

#	Features / Characteristics	Candidate Device	Predicate Device
1	Intended Use	LIFECODES LSA Class II is a bead-based immunoassay used to qualitatively detect HLA IgG antibodies to aid donor and recipient matching in transfusion or transplantation. Luminex Instrument and XY Platform are required to run the LIFECODES Class II assay. The MATCH IT! Antibody Software is intended as an aid in the analysis of LIFECODES and Class II assay.	LABScreen products are intended for use in detection of HLA antibody using flow cytometric technology
23	Technology	Flow Cytometric Technology	Flow Cytometric Technology
3	Specimen Collection	Blood without anticoagulant (serum)	Serum or Plasma
4	Reportable Results	Qualitative assay; results are reported as positive or negative for each antigen present in the panel.	Assignment of antibody specificity by matching the reaction pattern to the known composition of the antigen panel
5	Packaging Configuration	24 Tests Kit	25 Tests Kit
6	Reagents		
	LSA Class II Beads Mix	A blend of beads each conjugated with a different single Class II HLA glycoprotein plus control beads.	LABScreen™ Class II Single Antigen Bead Mix

	LSA Conjugate Concentrate	Goat anti-Human IgG conjugated to phycoerythrin in a phosphate-based storage buffer containing NaCl, Tween2- and sodium azide.	PE-conjugated 2nd Ab (anti-Human IgG)
	LIFECODES Wash Buffer	A phosphate-based buffer containing NACl, Tween-20, sodium azide and bovine serum albumin.	LABScreen Wash Buffer – 10X
	LSA Class II Positive Control	This serum or sera blend is obtained from individual(s) shown to be alloimmunized to HLA antigens and will react with most of the LSA Class II beads.	N/A
	LSA Class II Negative Control	This serum or sera blend is obtained from individual(s) known to have no antibodies to HLA antigens and will react with few if any of the LSA Class II beads.	Negative Control Serum (for HLA)
7	Instructions for Use (IFU)	LIFECODES LSA Class I and LIFECODES LSA Class II Product Insert	One Lambda LABScreen Product Insert

7. Performance Testing

The performance of both LIFECODES® LSA™ (LSA1) and LIFECODES® LSA™ Class II (LSA2) was verified and testing demonstrates safety and effectiveness.

TESTING	AGREEMENT
Immucor GTI Diagnostics, Inc.	
Performance Evaluation	LSA1 vs LABScreen Single Antigen HLA Class I Combi
Accuracy Study	
75 Positive sera and 76 Negative sera tested; Lower one sided 95% confidence interval is listed	
Co-Positivity	79.6%
Co-Negativity	97.0%
Agreement	93.4%
Interfering Substance Study - Exogenous	
This study demonstrated 12 substances showed no interference in LSA1 or LSA2. Refer to product insert for the list of compounds and the concentrations. Target for lower one sided 95% confidence interval is listed	
High Positives	≥ 95%
Low Positives	≥ 90%
All Calls	≥ 95%
Interfering Substance Study - Endogenous	
This study demonstrated triglycerides, hemoglobin and IgM show no interference in LSA1 or LSA2. Refer to product insert for the acceptable concentrations. Target for lower one sided 95% confidence interval is listed unless indicated otherwise.	
High Positives	≥ 95%
Low Positives	≥ 90% (Point Estimate)
All Calls	≥ 95%
Lot-to-Lot Reproducibility Study	
4 Lots of LSA1 giving 100% antigens of three separate lots. 9 positive sera and 1 high negative sera were tested in 6	

replicates.			
High Positives		100% for (4/4) lots	
Low Positives		99.9% for (4/4) lots	
Negatives		100% for (4/4) lots	
High Negatives		100% for (4/4) lots	
Three Sites including two HLA Clinical Laboratories and One Internal Site (Immucor)			
Performance Evaluation		**Lower one sided 95% confidence interval is listed**	
	Positive Agreement	Negative Agreement	Overall Agreement
Initial Testing (three sites)	79%	98%	94%
After Discrepant Resolution	97%	99%	99%
Comparison of LSA I to Epitope Analysis			
LSA Unique Beads	75%	97%	93%
Reproducibility Study			
Testing was conducted at three sites. Each site provided two operators and testing consisted of two runs per day over five non-consecutive days. 5 positive, 1 negative and 1 high negative samples were tested in triplicate. Following data is the observed vs the expected results by sample.			
High Positives		>99%	
Low Positives		94%	
Negatives		>99%	
High Negatives		96%	
Reproducibility Study - 2			
A second study was performed using 94 clinical samples comparing internal results to results from an external site. The 94 samples are a sub-set of the samples used in the Accuracy Study. The lower one sided 95% confidence interval is listed.			
Positive Percent Agreement		91.70%	
Negative Percent Agreement		98.88%	
Overall Agreement		96.53%	

TESTING	AGREEMENT
Immucor GTI Diagnostics, Inc.	
Performance Evaluation	LSA2 vs LABScreen Single Antigen HLA Class II Group 1
Accuracy Study	
75 Positive sera and 75 Negative sera tested ; Lower one sided 95% confidence interval is listed	
Co-Positivity	63.0%
Co-Negativity	96.0%
Agreement	89.9%
Interfering Substance Study - Exogenous	
This study demonstrated 12 substances showed no interference in LSA1 or LSA2. Refer to product insert for the list of compounds and the concentrations. Target for lower one sided 95% confidence interval is listed.	
High Positives	≥ 95%
Low Positives	≥ 90%
All Calls	≥ 95%
Interfering Substance Study - Endogenous	
This study demonstrated triglycerides, hemoglobin and IgM show no interference in LSA1 or LSA2. Refer to product	

insert for the acceptable concentrations. Target for lower one sided 95% confidence interval is listed unless indicated otherwise.			
High Positives		≥ 95%	
Low Positives		≥ 90% (Point Estimate)	
All Calls		≥ 95%	
Lot-to-Lot Reproducibility Study			
5 Lots of LSA2 giving 79.2% antigens of three separate lots			
High Positives		100%	
Low Positives		99.9%	
Negatives		99% for (5/5) lots, 100% for (4/5) lots	
High Negatives		98.6	
Three Sites including two HLA Clinical Laboratories and One Internal Site (Immucor)			
Performance Evaluation		Lower one sided 95% confidence interval is listed	
	Positive Agreement	Negative Agreement	Overall Agreement
Initial Testing (three sites)	69%	96%	91%
After Discrepant Resolution	97%	98%	98%
Comparison of LSA II to Epitope Analysis			
LSA Unique Beads	73%	97%	93%
Reproducibility Study			
Testing was conducted at three sites. Each site provided two operators and testing consisted of two runs per day over five non-consecutive days. 5 positive, 1 negative and 1 high negative samples were tested in triplicate. Following data is the observed vs the expected results by sample.			
High Positives		>99%	
Low Positives		97%	
Negatives		>99%	
High Negatives		98%	
Reproducibility Study - 2			
A second study was performed using 94 clinical samples comparing internal results to results from an external site. The 94 samples are a sub-set of the samples used in the Accuracy Study. The lower one sided 95% confidence interval is listed.			
Positive Percent Agreement		93.36%	
Negative Percent Agreement		98.84%	
Overall Agreement		97.77%	

Conclusion

The internal and external studies conclude both LIFECODES LSA Class I and LIFECODES LSA Class II are safe and effective. All data submitted is complete and supports LIFECODE LSA Class I is substantially equivalent to One Lambda LABScreen Single Antigen Class I Combi and LIFECODES LSA Class II is substantially equivalent to One Lambda LABScreen Single Antigen Class I Group 1.