510(k) Summary

1. **Submitter**

Owner's Name:	Immucor GTI Diagnostics, Inc.
Address:	20925 Crossroads Circle, Waukesha, WI 53186
Phone:	(262) 754-1000
Establishment Registration Number:	2183608
Name of Contact Person:	Amy Cochran, Regulatory Affairs Specialist II

2. **Name of Device**

Device Name:	LIFECODES® LifeScreen XP
Classification:	Unclassified
Device Code:	MZI

3. **Name of Predicate Device for Claiming Equivalence**
LIFECODES LifeScreen Deluxe (BK160035)

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 LifeScreen XP Beads are designed to detect IgG antibodies to HLA Class I and Class II antigens. LifeScreen XP is composed of unique Luminex Beads to which affinity purified Class I HLA and Class II HLA glycoproteins are conjugated.

As a screening assay for the detection of HLA antibody, LIFECODES LifeScreen XP provide a wide range of HLA targets obtained from hundreds of donors and cell lines. Because the ability to detect an antibody (IgG) is dependent on the relative frequency of the target epitope, LIFECODES LifeScreen XP combines antigens to maximize the amount of related epitopes on each bead. For HLA Class I-coated beads, the antigens are selected and grouped based on serological cross-reactive groups (CREGs). For HLA Class II-coated beads, the antigens are selected and enriched based on loci: HLA-DR, HLA-DQ, and HLA-DP. Please review the LIMITATIONS OF THE PROCEDURE section for further details.

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 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 a negative control bead included in the bead preparation to determine if the bead is positive or negative for bound alloantibody.

5. Intended Use

LIFECODES LifeScreen XP is a manual, qualitative bead-based immunoassay used to detect IgG antibodies to HLA Class I and Class II molecules in patients sensitized to HLA by transfusion, pregnancy, or transplantation to aid donor and recipient matching in transfusion or transplantation. A Luminex Instrument is required to run the LIFECODES LifeScreen XP assay. The MATCH IT!® Antibody Software is an accessory intended as an aid in the analysis of LIFECODES LifeScreen XP assay. Laboratory professionals are the intended user of the device.

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 LifeScreen XP and the predicate device LIFECODES LifeScreen Deluxe. LIFECODES LifeScreen XP is a modification/ enhancement of the LIFECODES LifeScreen Deluxe product

Table 5-1

#	Features / Characteristics	Candidate Device (LIFECODES LifeScreen XP)	Predicate Device (LIFECODES LifeScreen Deluxe)	Comments
1	Intended Use	LIFECODES LifeScreen XP is a manual, qualitative bead-based immunoassay used to detect IgG antibodies to HLA Class I and Class II molecules in patients sensitized to HLA by transfusion, pregnancy, or transplantation to aid donor and recipient matching in transfusion or transplantation. A Luminex Instrument is required to run the LIFECODES LifeScreen XP assay. The MATCH IT!® Antibody Software is an accessory intended as an aid in the analysis of LIFECODES LifeScreen XP assay. Laboratory professionals are the intended user of the device. This kit is intended for *In Vitro* Diagnostic (IVD) use.	LIFECODES LifeScreen Deluxe is a qualitative bead-based immunoassay used to detect IgG antibodies to HLA Class I and Class II molecules. This kit is intended for *In Vitro* Diagnostic (IVD) use.	No change to the form/fit/function. The intent of product use did not change. However, the intended use statement was modified to add verbiage to clarify instrument / software / intended user to align with global regulatory requirements.

#	Features / Characteristics	Candidate Device (LIFECODES LifeScreen XP)	Predicate Device (LIFECODES LifeScreen Deluxe)	Comments
2	Technology	Bead based immunoassay using the Luminex technology	Bead based immunoassay using the Luminex technology	No Change
3	Specimen Collection	Blood without anticoagulant (serum)	Blood without anticoagulant (serum)	No Change
4	Reportable Results	Qualitative assay: results are reported as positive or negative	Qualitative assay: results are reported as positive or negative	No Change
5	Packaging Configuration	96 Tests Kit	96 Tests Kit	No Change
6	Kit Components			
LifeScreen XP Beads: The Class I Beads, Class II Beads, Control Beads and Storage Buffer are combined in a single vial	Class I Beads	1 bead conjugated with affinity purified antigen derived from platelets obtained from a pool of 300 donors 6 additional beads conjugated with purified antigen each derived from a pool of donors (6 - 11) which are enriched for Class I CREG reactivity.	1 bead conjugated with affinity purified antigen derived from platelets obtained from a pool of 300 donors 6 additional beads conjugated with purified antigen each derived from a pool of donors (6 - 11) which are enriched for Class I CREG reactivity.	No Change
	Class II Beads	1 bead conjugated with affinity purified antigen derived from 30 different EBV transformed cell lines 4 additional beads conjugated with purified antigen each derived from a pool of donors (5 - 8) which are enriched for DR and DQ loci reactivity.	1 bead conjugated with affinity purified antigen derived from 30 different EBV transformed cell lines 4 additional beads conjugated with purified antigen each derived from	Contains 2 additional beads conjugated with purified antigen each derived from a pool of donors (4 - 5), which are enriched for HLA-DP reactivity.

#	Features / Characteristics	Candidate Device (LIFECODES LifeScreen XP)	Predicate Device (LIFECODES LifeScreen Deluxe)	Comments
		Contains 2 additional beads conjugated with purified antigen each derived from a pool of donors (4 - 5), which are enriched for HLA-DP reactivity.	a pool of donors (5 - 8) which are enriched for DR and DQ loci reactivity	
	Control Beads	3 CON Beads conjugated with: No Antigen (Mock Beads), Human Serum Albumin or Human Platelet GPIV	3 CON Beads conjugated with: No Antigen (Mock Beads), Human Serum Albumin or Human Platelet GPIV	No Change
	Bead Blend Storage Buffer	Phosphate buffer containing NaCl, Tween-20, ProClin 300 and Bovine Serum Albumin	Phosphate buffer containing NaCl, Tween-20, ProClin 300 and Bovine Serum Albumin	No Change
Conjugate Concentrate		Solution containing: Phycoerythrin conjugated goat affinity purified antibody to human IgG in a stabilizer. Contains 0.1% sodium azide.	Solution containing: Phycoerythrin conjugated goat affinity purified antibody to human IgG in a stabilizer. Contains 0.1% sodium azide.	No Change
Wash Buffer		Phosphate buffer containing NaCl, Tween-20, ProClin 300 and Bovine Serum Albumin	Phosphate buffer containing NaCl, Tween-20, ProClin 300 and Bovine Serum Albumin	No Change
Positive Control Sera		Human serum containing antibodies to HLA Class I and Class II with addition of 0.1% sodium azide	Human serum containing antibodies to HLA Class I and Class II with addition of 0.1% sodium azide	No Change
Negative Control Sera		Human serum which does not contain any HLA antibodies with addition of 0.1% sodium azide	Human serum which does not contain any HLA antibodies with addition of 0.1% sodium azide	No Change

#	Features / Characteristics	Candidate Device (LIFECODES LifeScreen XP)	Predicate Device (LIFECODES LifeScreen Deluxe)	Comments
7	Instructions for Use (IFU)	LIFECODES LifeScreen XP Instructions For Use	LIFECODES LifeScreen Deluxe Instructions For Use	New IFU created for new product

7. Non-Clinical Studies Supporting Safety and Effectiveness of the Candidate Device

The following performance evaluation testing was proposed to FDA as part of pre-submission BQ190310 to demonstrate verification and validation of the proposed device. In written feedback dated February 28, 2019, the FDA deemed the testing acceptable. The performance of LIFECODES® LifeScreen XP was verified, validated, and testing demonstrates safety and effectiveness. A summary is below, additional detail is available in Section 018, Performance Testing – Bench.

TESTING	AGREEMENT
Immucor GTI Diagnostics, Inc.	
Method Comparison (Verification Testing):	
HLA Class I on the Luminex 200 instrument: LIFECODES LifeScreen XP vs. LIFECODES LifeScreen Deluxe 174 samples	
Positive Percent Agreement / 95% Confidence Interval, Lower Bound	98.8% / 94.6 %
Negative Percent Agreement / 95% Confidence Interval, Lower Bound	98.9% / 94.7 %
Overall Percent Agreement / 95% Confidence Interval, Lower Bound	98.9% / 96.4%
HLA Class II on the Luminex 200 instrument: LIFECODES LifeScreen XP vs. LIFECODES LifeScreen Deluxe 170 samples	
Positive Percent Agreement / 95% Confidence Interval, Lower Bound	98.7% / 94.0%
Negative Percent Agreement / 95% Confidence Interval, Lower Bound	98.9% / 95.0%
Overall Percent Agreement / 95% Confidence Interval, Lower Bound	98.8% / 96.3%
HLA Class I on the FLEXMAP 3D instrument: LIFECODES LifeScreen XP vs. LIFECODES LifeScreen Deluxe 166 samples	
Positive Percent Agreement / 95% Confidence Interval, Lower Bound	100% / 96.5%
Negative Percent Agreement / 95% Confidence Interval, Lower Bound	98.8% / 94.3%
Overall Percent Agreement / 95% Confidence Interval, Lower Bound	99.4% / 97.2%
HLA Class II on the FLEXMAP 3D instrument: LIFECODES LifeScreen XP vs. LIFECODES LifeScreen Deluxe 166 samples	
Positive Percent Agreement /	97.5% /

95% Confidence Interval, Lower Bound	92.3%
Negative Percent Agreement / 95% Confidence Interval, Lower Bound	100% / 96.6%
Overall Percent Agreement / 95% Confidence Interval, Lower Bound	98.8% / 96.3%
HLA Class I: LIFECODES LifeScreen XP Luminex 200 vs. FLEXMAP 3D 164 samples	
Positive Percent Agreement / 95% Confidence Interval, Lower Bound	100% / 96.5%
Negative Percent Agreement / 95% Confidence Interval, Lower Bound	98.7% / 94.1%
Overall Percent Agreement / 95% Confidence Interval, Lower Bound	99.4% / 97.1%
HLA Class II: LIFECODES LifeScreen XP Luminex 200 vs. FLEXMAP 3D 160 samples	
Positive Percent Agreement / 95% Confidence Interval, Lower Bound	100% / 96.2%
Negative Percent Agreement / 95% Confidence Interval, Lower Bound	98.8% / 94.4%
Overall Percent Agreement / 95% Confidence Interval, Lower Bound	99.4% / 97.1%
Stability Study – Accelerated (Verification Testing)	
The overarching purpose of the accelerated stability study was to demonstrate that the added HLA-DP enriched beads (CII-06 and CII-07) did not result in a reduction in the shelf life of the product. This objective was met.	
Stability Study – In-Use (Verification Testing)	
The results of this study demonstrated that the components of the LIFECODES LifeScreen XP assay maintain their activity and remain stable for 351 days after opening (in use) when stored under the conditions specified in the product insert.	
Precision Studies (Validation Testing)	
HLA Class I Repeatability (within run precision)	
Sample	% Concordance (95% LCL)
Negative Serum Sample 1	100% (90.5%)
Negative Serum Sample 2	100% (90.5%)
Low Positive Serum Sample 1	100% (90.5%)
Low Positive Serum Sample 2	100% (90.5%)
Moderate Positive Serum Sample 1	100% (90.5%)
Moderate Positive Serum Sample 2	100% (90.5%)
High Positive Serum Sample 1	100% (90.5%)
High Positive Serum Sample 2	100% (90.5%)
HLA Class II Repeatability (within run precision)	
Sample	% Concordance (95% LCL)
Negative Serum Sample 1	100% (90.5%)
Negative Serum Sample 2	100% (90.5%)
Low Positive Serum Sample 1	100% (90.5%)
Low Positive Serum Sample 2	100% (90.5%)
Moderate Positive Serum Sample 1	100% (90.5%)
Moderate Positive Serum Sample 2	100% (90.5%)
High Positive Serum Sample 1	100% (90.5%)

High Positive Serum Sample 2	100% (90.5%)
HLA Class I (within laboratory precision)	
Sample	% Concordance (95% LCL)
Negative Serum Sample 1	100% (95.1%)
Negative Serum Sample 2	100% (95.1%)
Low Positive Serum Sample 1	100% (95.1%)
Low Positive Serum Sample 2	100% (95.1%)
Moderate Positive Serum Sample 1	100% (95.1%)
Moderate Positive Serum Sample 2	100% (95.1%)
High Positive Serum Sample 1	100% (95.1%)
High Positive Serum Sample 2	100% (95.1%)
HLA Class II (within laboratory precision)	
Sample	% Concordance (95% LCL)
Negative Serum Sample 1	100% (95.1%)
Negative Serum Sample 2	100% (95.1%)
Low Positive Serum Sample 1	100% (95.1%)
Low Positive Serum Sample 2	100% (95.1%)
Moderate Positive Serum Sample 1	100% (95.1%)
Moderate Positive Serum Sample 2	100% (95.1%)
High Positive Serum Sample 1	100% (95.1%)
High Positive Serum Sample 2	100% (95.1%)
Within Device and Between Device Precision – Comparison of Luminex 200 to Luminex FLEXMAP 3D	
HLA Class I - Luminex FLEXMAP 3D (FM3D) Results compared to expected results	
Agreement	99.4%
Concordance (95% Lower CI)	97.1%
PPA (Point Estimate)	100%
PPA (95% Lower CI)	97.5%
NPA (Point Estimate)	97.5%
NPA (95% Lower CI)	88.7%
HLA Class II - Luminex FLEXMAP 3D (FM3D) Results compared to expected results	
Agreement	99.4%
Concordance (95% Lower CI)	97.1%
PPA (Point Estimate)	100%
PPA (95% Lower CI)	97.5%
NPA (Point Estimate)	97.5%
NPA (95% Lower CI)	88.7%
HLA Class I - Luminex FLEXMAP 3D (FM3D) Results compared to Luminex 200 (LX4.2) results	
Agreement	100%
Concordance (95% Lower CI)	98.6%
PPA (Point Estimate)	100%
PPA (95% Lower CI)	97.6%
NPA (Point Estimate)	100%
NPA (95% Lower CI)	92.6%
HLA Class II - Luminex FLEXMAP 3D (FM3D) Results compared to Luminex 200 (LX4.2) results	
Agreement	99.4%
Concordance (95% Lower CI)	97.1%
PPA (Point Estimate)	100%
PPA (95% Lower CI)	97.5%

NPA (Point Estimate)			97.5%	
NPA (95% Lower CI)			88.7%	
HLA Class I - Luminex FLEXMAP 3D (FM3D) Results compared to Luminex 200 (LX4.3) results				
Agreement			99.4%	
Concordance (95% Lower CI)			97.1%	
PPA (Point Estimate)			100%	
PPA (95% Lower CI)			97.5%	
NPA (Point Estimate)			97.5%	
NPA (95% Lower CI)			88.7%	
HLA Class II - Luminex FLEXMAP 3D (FM3D) Results compared to Luminex 200 (LX4.3) results				
Agreement			99.4%	
Concordance (95% Lower CI)			97.1%	
PPA (Point Estimate)			100%	
PPA (95% Lower CI)			97.5%	
NPA (Point Estimate)			97.5%	
NPA (95% Lower CI)			88.7%	
Lot to Lot Reproducibility				
HLA Class I – Luminex 200; Agreement, Percent Agreement, and (95% Lower Confidence Limit)				
Parameter	Lot 1		Lot 2	Lot 3
Concordance	160/160, 100% (98.1%)		160/160, 100% (98.1%)	160/160, 100% (98.1%)
PPA	120/120, 100% (97.5%)		120/120, 100% (97.5%)	120/120, 100% (97.5%)
NPA	40/40, 100% (92.8%)		40/40, 100% (92.8%)	40/40, 100% (92.8%)
HLA Class II – Luminex 200; Agreement, Percent Agreement, and (95% Lower Confidence Limit)				
Parameter	Lot 1		Lot 2	Lot 3
Concordance	160/160, 100% (98.1%)		160/160, 100% (98.1%)	160/160, 100% (98.1%)
PPA	120/120, 100% (97.5%)		120/120, 100% (97.5%)	120/120, 100% (97.5%)
NPA	40/40, 100% (92.8%)		40/40, 100% (92.8%)	40/40, 100% (92.8%)
HLA Class I – Luminex FLEXMAP 3D; Agreement, Percent Agreement, and (95% Lower Confidence Limit)				
Parameter	Lot 1		Lot 2	Lot 3
Concordance	159/160, 99.4% (97.1%)		160/160, 100% (98.1%)	160/160, 100% (98.1%)
PPA	120/120, 100% (97.5%)		120/120, 100% (97.5%)	120/120, 100% (97.5%)
NPA	39/40, 97.5% (88.7%)		40/40, 100% (92.8%)	40/40, 100% (92.8%)
HLA Class II – Luminex FLEXMAP 3D; Agreement, Percent Agreement, and (95% Lower Confidence Limit)				
Parameter	Lot 1		Lot 2	Lot 3
Concordance	159/160, 99.4% (97.1%)		160/160, 100% (98.1%)	159/160, 99.4% (97.1%)
PPA	120/120, 100% (97.5%)		120/120, 100% (97.5%)	120/120, 100% (97.5%)
NPA	39/40, 97.5% (88.7%)		40/40, 100% (92.8%)	39/40, 97.5% (88.7%)
Comparison of HLA-DP enriched bead (CLII-06 and CLII-07) to the other Class II beads				
Bead	Positive Agreement		Negative Agreement	
	No. Concordant	% Agreement (95% LCL)	No. Concordant	% Agreement (95% LCL)
CLII-01	720/720	100% (99.6%)	238/240	99.2% (97.4%)
CLII-02	720/720	100% (99.6%)	240/240	100% (98.8%)
CLII-03	720/720	100% (99.6%)	240/240	100% (98.8%)
CLII-04	720/720	100% (99.6%)	240/240	100% (98.8%)
CLII-05	720/720	100% (99.6%)	240/240	100% (98.8%)
CLII-06	720/720	100% (99.6%)	240/240	100% (98.8%)
CLII-07	720/720	100% (99.6%)	240/240	100% (98.8%)
Lot-to-lot variation in Median Fluorescence Intensity (MFI) – Comparison of HLA-DP enriched beads (CLII-06 and CLII-07) to the other Class II beads – Luminex 200				
	Probe II-01	Probe II-02	Probe II-03	Probe II-04	Probe II-05	Probe II-06	Probe II-07

Sample	%CV	%CV	%CV	%CV	%CV	%CV	%CV
High1	5.9	2.9	3.1	5.4	5.4	4.1	3.5
High2	3.0	NS*	NS*	NS*	0.5	1.0	NS*
Low1	9.5	5.2	2.9	5.8	9.3	10.3	5.6
Low2	10.7	4.7	4.0	7.1	7.7	6.1	2.9
Mod1	9.1	2.6	3.3	5.3	7.7	7.8	3.2
Mod2	10.5	7.3	7.5	11.3	10.5	8.8	9.5
Neg1	14.1	9.9	4.4	12.4	NS*	17.8	4.0
Neg2	41.0	8.3	41.0	16.2	15.8	10.2	13.5
Lot-to-lot variation in Median Fluorescence Intensity (MFI) – Comparison of HLA-DP enriched beads (CLII-06 and CLII-07) to the other Class II beads – Luminex FLEXMAP 3D							
	Probe II-01	Probe II-02	Probe II-03	Probe II-04	Probe II-05	Probe II-06	Probe II-07
Sample	%CV	%CV	%CV	%CV	%CV	%CV	%CV
High1	3.8	3.8	2.3	6.9	5.2	3.3	2.2
High2	NS*	3.2	3.3	3.5	NS*	2.7	2.6
Low1	10.1	8.5	6.1	10.1	11.7	15.1	10.3
Low2	3.9	NS*	NS*	NS*	N*S	NS*	NS*
Mod1	0.7	NS*	NS*	2.5	4.3	5.1	NS*
Mod2	4.1	NS*	2.5	4.9	5.7	2.0	1.7
Neg1	2.3	4.5	10.5	8.0	13.7	9.7	9.8
Neg2	22.4	11.8	27.6	9.1	9.8	NS*	23.6
Real-Time Stability Study (Validation Testing)							
The study is still in progress. An interim report was generated in December 2021. Lot 1 showed stability out to 330 days, which was the latest time point. Lot 2 showed stability out to 200 days, which was the latest time point. Lot 3 completed the Time-zero testing.							

*NS is equivalent to zero.

Conclusion

The internal studies conclude LIFECODES LifeScreen XP is safe and effective. All data submitted is complete and supports LIFECODES LifeScreen XP is substantially equivalent to LIFECODES LifeScreen Deluxe.