Modified 510(k) Summary for Lifecodes ID Class I and Lifecodes ID Class II

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR section 807.92

Submitter's Name: GTI, Inc.
Address: 20925 Crossroads Circle, Waukesha, WI 53186
Phone: 262.792.3900
Fax: 262.792.3919
Name of Contact Person: Ben Boldt, PhD
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This notification is being submitted by GTI, Inc., as the original developer and manufacturer of Lifecodes ID Class I and Lifecodes ID Class II, on behalf of Tepnel Lifecodes, formerly Orchid Diagnostics, the seller.

Device Name:
- Lifecodes ID Class I
- Lifecodes ID Class II

Proprietary Name:
- Lifecodes ID Class I: A Luminex^{100} screening assay for the qualitative detection of IgG panel reactive antibodies (PRA) to HLA Class I molecules
- Lifecodes ID Class II: A Luminex^{100} screening assay for the qualitative detection of IgG panel reactive antibodies (PRA) to HLA Class II molecules

Classification Name:
- Lifecodes ID Class I: A bead-based immunoassay to qualitatively detect IgG panel reactive antibodies (PRA) to HLA Class I molecules
- Lifecodes ID Class II: A bead-based immunoassay to qualitatively detect IgG panel reactive antibodies (PRA) to HLA Class II molecules

Summary and Explanation: 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 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.

Description: Lifecodes ID Class I and Lifecodes ID Class II are designed to detect IgG panel reactive antibodies to HLA Class I and Class II molecules, respectively. The assays utilize unique Luminex^{100} beads to which affinity purified Class I HLA (ID Class I) or Class II HLA (ID Class II) glycoproteins have been conjugated.

An aliquot of the Lifecodes ID Class I beads or Lifecodes ID Class II 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^{100} instrument. To determine if a specific HLA bead is positive or negative for bound alloantibody, the signal intensity of the specific bead is compared to the signal intensity of four different beads: three non-HLA beads and the HLA-conjugated bead with the lowest signal intensity. A specific bead is considered positive when it is scored as positive for a minimum of two of the four control beads. The total numbers of HLA beads that are positive are expressed as a percentage of the total number of HLA beads (%PRA).

Intended Use:
- Lifecodes ID Class I is used to qualitatively detect IgG panel reactive antibodies to HLA Class I molecules. This kit is intended for *In Vitro* Diagnostic (IVD) use.
- Lifecodes ID Class II is used to qualitatively detect IgG panel reactive antibodies to HLA Class II molecules. This kit is intended for *In Vitro* Diagnostic (IVD) use.