510(k) Summary of Safety and Effectiveness

Company Name: Invitrogen Corporation

Device Name: Invitrogen HLA *AllSet*$^{+™}$ Gold SSP

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Summary Date: March 21, 2007

Common Name: HLA Typing Kit

Classification Name: HLA Typing Kits are Unclassified

Predicate Device (s) : Invitrogen Corporation HLA Low Resolution SSP UniTray® BK000019, Invitrogen Corporation HLA High Resolution SSP UniTray® BK020068, UniMatch® Plus BK030003.

1.0 Description of Device

The Invitrogen HLA *AllSet*$^{+™}$ Gold SSP is a PCR-based method designed to provide low to high resolution of the various HLA Class I and II subtypes. Formulations of allele or group specific primer sets are used to amplify genomic DNA using an 8-96 well thermal tray (dependant upon number of primer mixes in kit). Setup includes mixing a reaction buffer with a human genomic DNA sample and Taq DNA Polymerase, dispensing the mixture into the tray, sealing and then thermal cycling. After cycling is complete, the PCR products are loaded onto a 2% agarose gel for electrophoresis. After electrophoresis, the ethidium bromide stained gel is photographed and interpreted using a worksheet for the specific amplification patterns. The test can be completed in 2.5 hours post DNA isolation. The test time varies depending on make and model of the thermal cycler used.

2.0 Intended use of Device

The Invitrogen Corporation HLA *AllSet*$^{+™}$ Gold SSP is a PCR based HLA typing evaluation method designed to provide resolution of the HLA Class I (A, B, C) and Class II (DRβ, DQβ) Loci using genomic DNA. This is the same intended use as the HLA Low and High Resolution SSP UniTray® Test Kits.

3.0 Technological Characteristics

The *AllSet*$^{+™}$ Gold SSP method is based on previously published sequence specific primer amplification methods (SSP). The primer sets amplify the alleles described by the international nomenclature committee of WHO. The process and technology of the ReadySet™ SSP is the same as the predicate devices: Low Resolution SSP UniTray® and High Resolution SSP UniTray®.

4.0 Data Summary

The verification of the performance of the HLA *AllSet*$^{+™}$ Gold SSP Test Kit was verified using three methods:

1) Verification of correct allele typing was performed by comparing results of testing reference DNA samples using the HLA *AllSet*$^{+™}$ Gold SSP Test Kit and using the comparable HLA SSP UniTray® Test Kit. Three comparable kit types were chosen to test inclusive of Class I Loci B and C and Class II Loci DQ. International Histocompatibility Working group (IHW) and Terasaki (TER) gold standard DNA samples were evaluated with the HLA *AllSet*$^{+™}$ Gold SSP Test Kit and the comparable HLA SSP UniTray® Test Kit. DNA samples were selected based on allele frequency and sample availability. The degree of comparable kit to kit concordance was 100%.
2) Verification of correct allele typing was performed by comparison of HLA *AllSet*$^{+™}$ Gold SSP Test Kit results to 17 reference DNA samples. International Histocompatibility Working group (IHW) and Terasaki (TER) gold standard DNA samples consisting of Alleles in the Class I Loci B and C and Class II Loci DQ were evaluated with the HLA *AllSet*$^{+™}$ Gold SSP Test Kit. DNA samples were selected based on allele frequency and sample availability. The allele typing results from the HLA *AllSet*$^{+™}$ Gold SSP Test Kit were verified to the IHW and TER gold standard previously typed DNA results. The degree of Group and Allele concordance was 100 %.
3) Verification of correct allele typing as compared to the results indicated by the UniMatch® Plus software was performed by comparison of the HLA *AllSet*$^{+™}$ Gold SSP

Test Kit results using the manual worksheets provided with the kit to the data output from the UniMatch® Plus software. The allele typing results from the HLA ***AllSet+™*** Gold SSP Test Kit manual worksheets were verified to the data output sheets from the UniMatch® Plus software. The degree of Worksheet to UniMatch® Plus software data output concordance was 100 %.

5.0 Conclusions

The intended use and technology of the HLA ***AllSet+™*** Gold SSP Test Kit is the same as the predicate HLA Low and High Resolution SSP UniTray® Test Kits. No new questions of safety or effectiveness are raised.