

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: BK050003

Submitted by

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Trade Name: LIFECODES HLA-SSO Typing Kits

Common Name: HLA-SSO Typing Kits

Classification Name: Unclassified

Predicate Device

510(k) Number: BK000019

Trade Name: PEL-FREEZ® SSP UniTray®

Description of the Device

The LIFECODES HLA-SSO Typing Kits are used to determine an individual's HLA type. The kits utilize 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 five kits, one each for typing the HLA-A, HLA-B, HLA-C, HLA-DQB 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 the 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.

Summary of Substantial Equivalence

PERFORMANCE

When LIFECODES HLA-SSO Typing Kits are used according to the procedure described in the product insert, the Class I and Class II HLA type of DNA samples can be determined. The HLA-A, HLA-B, HLA-C, and HLA-DQB kits showed 100% positive agreement with results obtained using the predicate device (SSP method). The HLA-DRB kit showed 100% positive agreement for DRB1 and DRB5 and 98% positive agreement for DRB3 and DRB4 with results obtained using the predicate device (SSP method).

STABILITY/SHELF LIFE

Stability data supports the current shelf life of at least one year.

REPRODUCIBILITY

Results of fifty DNA samples typed using the LIFECODES Typing Kits at two testing sites showed 96% reproducibility.

Intended Use: DNA typing of Class I and Class II HLA Alleles