

510(k) Summary

Date of application:

June 28, 1996

Manufacturer Name and address:

One Lambda, Inc.
21001 Kittridge Street
Canoga Park, CA 91303

Registration Number:

2024375

Contact Person:

Don G. Aarii

Telephone and FAX numbers:

818-702-0042

818-702-6904 (fax)

Device Name:

Micro SSP HLA Class II DNA Typing Kit

510(k) Number:

Not assigned a BK number yet.

Classification:

Class I

Description of the Device:

Micro SSP HLA Class II DNA Typing Kit provides sequence-specific primers (SSP) for the amplification of DR β 1 and DQ β 1 alleles of the HLA Class II gene locus by the process of polymerase chain reaction (PCR)

Intended Use:

DNA typing of HLA Class II alleles for organ transplantation, paternity, or forensic applications.

Summary of Appendix Information included in this package:

Cover letter giving a summary of safety and effectiveness as well as a statement of substantial equivalence with supporting documentation in appendix 6.

APPENDIX 1

Accuracy of Micro SSP HLA Class II DNA Typing Kit results with gold standard cell lines

DNAs from gold standard cell lines (UCLA cell exchange) were typed using the Micro SSP HLA Class II DNA Typing Kit. The data show a 100% concordance over 67 samples. Every cell in this gold standard has been typed by the major DNA HLA typing Laboratories in the world. These cell lines are considered the standard.

APPENDIX 2

Reproducibility Test

Three DNAs from the gold standard cell lines (UCLA cell exchange) were typed using the Micro SSP HLA Class II DNA Typing Kit between 5 and 11 times. The data show 100% reproducibility.

APPENDIX 3

Reagent Stability Test

DNAs from the gold standard cell lines (UCLA cell exchange) were typed using the Micro SSP HLA Class II DNA Typing Kit which had been stored at -65°C for a two month period. The data show a 100% concordance over 30 samples indicating stability of the reagents for over 2 months. It is a well known accepted fact that dried down oligos are stable for long periods of time at least up to a year.

APPENDIX 4

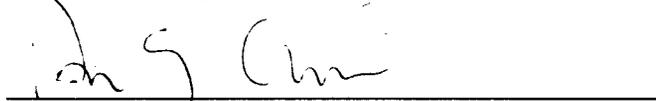
Product Insert

APPENDIX 5

Product Labeling

APPENDIX 6

Reports of the typing results of the cell lines



Don G. Arii
Vice President