

Attachment F

510(k) Summary of Safety and Effectiveness

Summary of Safety and Effectiveness

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Summary Date: December 26, 2002

Trade Name: UniMatch™ Plus

Common Name: HLA Typing Software

Classification Name: UniMatch™ Plus is an accessory to HLA typing kits. HLA typing kits are not yet classified, but are reviewed as Class II devices within the Center for Biological Devices.

Predicate Device(s):

510(k) Number: BK000019
Manufacture: PEL-FREEZ Clinical Systems, LLC®
Trade Name: PEL-FREEZ® HLA Low Resolution SSP UniTray®

510(k) Number: BK960092
Manufacture: One Lambda
Trade Name: One Lambda DNA/LMT Software

1.0 Description of Device

When HLA typing is performed, a significant amount of information is provided with regard to matching alleles. Without a software aide to support evaluation of the HLA typing results, evaluation is completed by filling in a Worksheet provided with the HLA typing kit.

UniMatch™ Plus is provided to the HLA typing kit user as a convenient aide to support evaluation of HLA typing results. UniMatch™ Plus performs the same function as the Worksheet for evaluation of HLA typing.

UniMatch™ Plus consists of two main components:

- 1) UniMatch™ Plus application software,
- 2) UniMatch™ Plus database file.

The UniMatch™ Plus application software can be installed and operates on the user's personal computer. The UniMatch™ Plus application software operates with a Windows® 95/98, 2000, ME, NT or XP operating systems. The UniMatch™ Plus application software operates as a program under these operating systems.

The UniMatch™ Plus database file is provided with each lot of HLA typing kits. The UniMatch™ Plus database file provides the information to support HLA typing for the lot. The results from UniMatch™ Plus are displayed on the computer display, can be printed on the computer system printer and stored for future reference.

2.0 Intended Use

UniMatch™ Plus is an accessory to HLA typing kits. The indication for use of UniMatch™ Plus is consistent with the use of HLA typing kits. The indications for use of UniMatch™ Plus are:

"UniMatch™ Plus supports evaluation of HLA typing results."

3.0 Technological

UniMatch™ Plus operates on a personal computer. The personal computer has to be operating under Windows® 95/98, 2000, ME, NT or XP operating systems.

4.0 Conclusions

The indications, intended use and technology of UniMatch™ Plus is substantially equivalent to the predicate devices. No new questions of safety or effectiveness are raised.