



MEMORANDUM

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Biologics Evaluation and Research

Date: February 21, 2003

To: File of BK030003
Device: UniMatch™ Plus
Sponsor: PEL-FREEZ Clinical Systems, LLC
Contact: Brian Loeffler, Director of Operations

From: Linda Weir, Software Reviewer, Devices Review Branch

Subject: Review memo and SE recommendation for BK030003, PEL-FREEZ UniMatch Plus

CC: Sheryl A. Kochman, Chief, Devices Review Branch
Darcel Bigelow, Software Reviewer, Devices Review Branch
Nadine Brock, Software Reviewer, Devices Review Branch
Teresita Mercado, CSO, Devices Review Branch

I. Background:

I reviewed the December 26, 2002 submission for BK030003, UniMatch™ Plus, Verion 1.0 from PEL-FREEZ Clinical Systems, LLC. The submission is for HLA typing software to be used as an accessory to the PEL-FREEZ® HLA typing kits. This submission was a traditional 510(k) and consisted of one volume. The predicate devices were stated to be the HLA typing worksheet included in BK000019, PEL-FREEZ® HLA Low resolution SSP UniTray®, and the HLA evaluation software included in the One Lambda Micro SSP HLA Class II DNA Typing kit. The HLA typing worksheet is not a device and therefore is not an acceptable predicate; however, the One Lambda Micro SSP HLA Class II DNA typing kit was cleared to distribute software to be used to interpret the DNA typing results obtained by the use of their kit and is acceptable as a predicate.

Level of Concern

This device is a minor level of concern device and was reviewed as such. Note that HLA typing is one of at least two methods of tissue typing applied. A second method is applied to assure close tissue typing, i.e. crossmatching.

Intended Use

The submission states that UniMatch™ Plus is an accessory to PEL-FREEZ HLA typing kits and is used to support the evaluation of HLA typing results. UniMatch Plus has the following features:

- Point and click data entry
- Performs multi-field search including allele search of saved typing results
- Use with Sequence Specific Primer (SSP) HLA typing kits
- Archive sample typing results
- Assigns National Marrow Donor Program (NMDP) codes and serologic equivalents

Device Description

UniMatch™ Plus is software to support the evaluation of HLA typing results. Instead of using a worksheet, the user enters the HLA typing results (positive lanes) from the electrophoretic patterns obtained with the PEL-FREEZ HLA typing kit. The computer analyzes the positive lanes with the use of an algorithm to determine if a perfect match is obtained. Additional analysis has to be performed if a perfect match cannot be assigned. Results can then be printed and archived.

The device has two major components; the UniMatch™ Plus application software and the UniMatch™ Plus database file. The application software is written in Visual Basic, can be installed on the user's personal computer and runs with Windows® 95/98, 2000, ME, NT or XP systems. The UniMatch Plus database file used MicroSoft Access. In addition to allele assignment, the software also assigns National Marrow Donor Program (NMDP) codes and serologic equivalents. The database file is provided with each new lot of HLA typing kit or when there is a change due to an update of the reference library of known HLA types.

II. Review Documentation-Additional Information requested from the sponsor:

Review of the December 26, 2003 submission required additional information from the sponsor before a recommendation could be made. The sponsor provided the additional information in February 14 and 18, 2003 faxes.

III. Items Reviewed:

The following areas were reviewed and deemed acceptable:

- Labeling
- Truthful and Accurate Statement
- Intended Use

- Substantial Equivalence Table
- 510(k) Summary
- Risk Analysis
- Architectural Diagram
- Functional Requirements
- Testing
- Algorithm used by software device to determine match
- Limitations
- Outstanding Anomalies

III. Recommendation:

I recommend a determination of substantial equivalence be made.

Reviewed by:

Date: