

BK980015

510(k) SUMMARY

April 21, 1998

Device Establishment

One Lambda, Inc.
21001 Kittridge Street
Canoga Park, California 91303
818-702-0042 (tel)
818-702-6904 (fax)

Contact person - Don Arii

Device trade or proprietary name -

FlowPRA

Device common or usual name or classification -

FlowPRA

Establishment registration number -

2024375

Class of device:

Class I

Claiming equivalence to:

Lambda Cell Tray - BK840013

Description of the Device

The FlowPRA™ Screening Test is designed for flow cytometric screening of panel reactive antibody (PRA) against HLA using a panel of FlowPRA beads, which are microparticles (2-4µm in diameter) coated with purified HLA antigens.

Intended Use

The FlowPRA Screening Test is intended for use in flow cytometric detection of HLA-specific antibodies in serum.

Summary of Substantial equivalence

FlowPRA and LCT is intended to detect the presence of HLA antibodies in a serum sample. The mechanism for attachment is the same. The HLA antibody will attach to the complementary antigen of a HLA specificity. In the case of the FlowPRA the HLA antigen is attached to the bead and in the case of the LCT the antigen is attached to the lymphocyte. The detection method is different. FlowPRA will detect the attached antibody with the use of a Flow Cytometer and the LCT by use of the microcytotoxicity test. The data received in both cases will be used to calculate the % PRA for the serum sample.

The methodology of detecting the HLA antigen and antibody attachment is different but the ending results are the same, %PRA.

Summary of Intended Use as compared to the predicate device

The FlowPRA Screening Test has the same intended use as the Lambda Cell Tray (LCT) which is to determine the presence of HLA antibodies in human serum. Both tests have 30 cells (bead) panel. Both tests can determine the percent PRA (%PRA). Studies showed a good correlation between the two tests on the % PRA detected from randomly selected patient sera.

Summary of Comparison between FlowPRA and LCT

Comparison of the FlowPRA test to the marketed LCT tests is listed in Table 1 and 2 which showed R values of over 80%.

Summary of Technological Characteristics

The technology of FlowPRA utilizes flow cytometry based technique for HLA antibodies detection and obtains statistically similar results as the predicted device LCT. This test utilizes a flow cytometer for data analysis. We have compared different flow cytometers in different laboratories which all gives comparable results.