

5 510(k) Summary

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Device Establishment

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Device trade or proprietary name -

XM-ONE® Transplantation Cross Match

Device common or usual name or classification -

XM-ONE®

Establishment registration number -

Will be done within 30 days after clearance

Class of device:

Unclassified, IVD general

Claiming equivalence to:

FlowPRA

Intended Use

XM-ONE® is an in vitro diagnostic kit which is used for the isolation of endothelial precursor cells and preparation of samples for analysis of IgM and IgG antibodies specific for these cells.

Summary of Substantial equivalence

XM-ONE and FlowPRA are intended to detect the presence of antibodies in a serum sample. The mechanism for attachment is the same. The antibody will attach to the complementary antigen. In the case of the XM-ONE the antigen is attached to a cell which is isolated using a magnetic bead and in FlowPRA the antigen is attached to a bead. The detection method is the same; both products detect the attached antibody with the use of a Flow Cytometer.

Summary of Intended Use as compared to the predicate device

XM-ONE and The FlowPRA Screening Test has the same intended use which is to determine the presence of antibodies in human serum. XM-ONE has the capability of detecting antibodies against HLA molecules as well other antigens expressed on the cell while FlowPRA only detects antibodies against HLA molecules. Both tests will be used in organ transplant patients

Summary of Comparison between XM-ONE and FlowPRA

Comparison of the XM-ONE test to the marketed FlowPRA tests is listed in Table enclosure chapter 18.1.4.

73 unknown sera from transplant patients were tested and FlowPRA detected donor specific antibodies in 3 patients and all of these patients also tested positive in XM-ONE. In addition XM-ONE detected endothelial specific antibodies in several patients.

Summary of Technological Characteristics

The technology of XM-ONE[®] utilizes magnetic beads to isolate cells from the donor and the predicate device uses beads coupled to antigens. These cells or beads are used in a flow cytometry based technique for detection of donor specific antibodies against the antigens attached to the reagent. We have performed a study in which the XM-ONE[®] test have been compared to the predicate device as well as to the de facto standards (lymphocyte cross matches) at 6 different clinical centers (Johns Hopkins, Mass General Hospital, Ohio State University Medical Center, Baylor Health, Karolinska University Hospital and Sahlgrenska University Hospital) with comparable results in all centers.