## 510(k) Summary

**Applicant Information:**


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| Date Prepared: | April 13, 2004 |
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**Device Information:**

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|---|---|
| Trade Name: | Capture-R® Select |
| Common Name: | Solid Phase Test System (Microtitration Plates) |
| Classification: | Class I |
| Classification Name: | Supplies/Blood Bank |
| Classification Number: | KSS |

**Device Description and Intended Use:**
The Capture-R® Select Solid Phase System provides modified microwells for the immobilization of human erythrocytes for use in solid phase assays for the detection of IgG red cell antibodies to corresponding red cell antigens (e.g., antibody screening, selected red cell panels, crossmatching, or antigen phenotyping).

**Predicate Device:**
Modified Capture-R reviewed under BK960017 dated 6/30/98.

**Comparison to Predicate Device:**
Capture-R Select is functionally equivalent to the currently marketed Modified Capture-R reviewed under BK960017 dated 6/30/98.

- The Modified Capture-R wells are coated with a chemical coupling agent to immobilize red cells to the microwell surface.
- Capture-R Select wells are coated with an immunologic agent to immobilize red cells to the microwell surface

Each device uses the same Capture reagents and test methods for the detection of IgG red cell antibodies.

**Summary of Non-Clinical Test Results.**
Evaluation of Capture-R Select compared to Modified Capture-R demonstrates the effective immobilization of human red cells for:

- Screening or the detection of IgG antibodies with 100% concordance.
- Detecting donor/patient incompatibility due to IgG antibodies with 100% concordance.

Stability studies demonstrated that the Capture-R Select antibody-red cell binding mechanism is unaffected by:

- Room temperature storage for up to 6 months and routine exposure to laboratory conditions of use.
- Comparison studies demonstrated acceptable monolayers can be formed with the use of patient or donor red cells collected in EDTA for up to 14 days and red cells collected in ACD, CPD, CP2D and CPDA-1 for up to 35 days.

Capture-R Select is a suitable component for the preparation of selected cell panels to assist in IgG antibody identification. Capture-R Select produced reproducible results when testing challenge antibody samples with both washed cells and whole blood.

**Summary of Clinical Test Results:**

The clinical data supports the use of Capture-R Select for performing IgG crossmatch, DAT and antigen phenotyping. The Capture-R Select is used in the following assays on the Galileo instrument: Weak_D, IgG Crossmatch (IgG_XM) and DAT. A comparison of test results by the Galileo method to the reference method was performed for each assay and is detailed in Table 1. The number of samples reported as "no interpretation", "discrepant" and the percent agreement to the reference method was calculated for the assays performed on the Galileo.

**Table 1: Initial Test Results:**

| Assay | Number of Samples Tested | Number of No Interpretation Results | Number of Discrepant Results | % Agreement to Reference Method |
|---|---|---|---|---|
| Weak_D | 568 | 14 | 3 | 97.0 |
| IgG_XM | 50** | 0 | 3 | 94.0 |
| DAT | 137 | 0 | 2 | 98.5 |

* 50 Patient/Donor Combinations (10 patients using 35 donor units)

The samples reported as "No Interpretation of Results" included sample results flagged as invalid (INV) due to automated process controls. The instrument is designed to give no interpretation when it detects conditions that could compromise the accuracy of results such as sample condition (excessive hemolysis, icterus, lipemia), clots or liquid level detection errors. Results flagged as invalid are considered a safety control to prevent the reporting of incorrect results. The samples reported as "Discrepant" included samples demonstrating different test interpretations between the Galileo method and the reference method.

Comparison of the Capture-R Select test results by the Galileo method to the expected results was performed for each assay after repeat testing. Samples which did not give an interpretation (i.e. hemolyzed, lipemic, icteric, etc) or samples associated with a limitation of the reagent (as specified in reagent labeling) were excluded from the study. The comparison by assay is detailed in Table 2.

**Final Test Results after Repeat Testing:**

| Assay | Number of Samples After Exclusions | Number of No Interpretation Results | Number of Discrepant Results | % Agreement to Expected Results |
|---|---|---|---|---|
| Weak_D | 561 | 0 | 0 | 100.0 |
| IgG_XM | 50* | 0 | 0 | 100.0 |
| DAT | 137 | 0 | 1 | 99.3 |

* 50 Patient/Donor Combinations (10 patients using 35 donor units)

**Conclusions Drawn from Studies**

The results of the non-clinical and clinical validation support the conclusion that the Capture-R Select is safe and effective and is substantially equivalent to the currently marketed device, Modified Capture-R.