# 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: _____.

1. **Submitter:**

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2. **Contact Person and Address:**

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3. **Preparation Date:**

   February 23, 2021

4. **Device Name:**

   **Trade Name or Proprietary name**
   ORTHO VISION® Max Analyzer

   Classification:
   Automated blood grouping and antibody test system, (864.9175), Class II

   Product Code:
   KSZ

5. **Predicate Device** ORTHO VISION Max Analyzer (BK190399)

6. **Registration Number:** The establishment number for the ORTHO VISION Max Analyzer is 2250051.

**7. Device Description:**

The modification to the ORTHO VISION Max Analyzer is for the addition of the Immediate Spin Crossmatch (ISXM) test.

The addition of the ISXM test to the ORTHO VISION Max Analyzer test menu requires a modification to the analyzer Assay Data Disk (ADD). The ADD is a data file which contains processing parameters used by the analyzer software. There are no changes required to the analyzer software or hardware for this ADD modification.

The ISXM test is used to detect the presence of blood group antibodies in an intended recipient's serum/plasma directed towards antigens present on donor red blood cells. In the gel test, the donor red blood cells are combined with recipient serum/plasma in the upper reaction chamber of the microtube of an MTS™ Buffered Gel Card. The gel card is centrifuged and examined for agglutination. Agglutination indicates the presence of an antigen/antibody reaction while lack of agglutination indicates the absence of an antigen/antibody reaction. Agglutinated red blood cells become trapped in the gel at various levels within the microtube, depending on the size of the agglutinates. Free nonagglutinated red blood cells pass through the gel and form a button of red blood cells on the bottom of the microtube.

**8. Device Indications For Use:**

ORTHO VISION Max Analyzer is an instrument designed to automate in vitro immunohematology testing of human blood utilizing ID-MTS gel card technology. ORTHO VISION Max Analyzer automates test processing functions including liquid pipetting, reagent handling, incubation, centrifugation, reaction grading and interpretation, and data management requirements using cards and digital image processing. ORTHO VISION Max Analyzer can be used as a standalone instrument or interfaced to the customer’s Laboratory Information System (LIS).

## 9. Comparison to predicate device

Table 1 Comparison to predicate device

| Characteristic | Predicate Device: (ORTHO VISION Max Analyzer BK190399) | Modified Device: (ORTHO VISION Max Analyzer) |
|---|---|---|
| Intended Use | ORTHO VISION Max Analyzer is an instrument designed to automate in vitro immunohematology testing of human blood utilizing ID-MTS gel card technology. ORTHO VISION Max Analyzer automates test processing functions including liquid pipetting, reagent handling, incubation, centrifugation, reaction grading and interpretation, and data management requirements using cards and digital image processing. ORTHO VISION Max Analyzer can be used as a standalone instrument or interfaced to the customer's Laboratory Information System (LIS). | Same |
| Classification | Name: Automated blood grouping and antibody test system<br>Device Class: II<br>Product Code: KSZ<br>Regulation Number: 21 CFR 864.9175 | Same |

| | | |
|---|---|---|
| Test Method | Column agglutination technology using ID- MTS Gel cards and reagents | Same |
| Reaction Grading | Digital Image Capture and Analysis for reaction grading | Same |
| Result Interpretation | According to pre-defined rules as part of the software | Same |
| Image | High resolution color image | Same |
| Barcode Symbologies | • Codabar<br>• ISBT 128<br>• Code 128<br>• Code 3 of 9<br>• Code 2 of 5 (Interleaved) | Same |
| Laboratory Information System | Bidirectional | Same |
| Test Menu | ISXM test is not available | Addition of ISXM test |

**10. Performance Testing:**

Testing evaluated the agreement between the ORTHO VISION Max Analyzer ISXM test versus expected values established by two licensed FDA reagents. The validation was conducted at one internal site located at Ortho Clinical Diagnostics, Rochester NY.

Overall concordance met the acceptance criteria for the point estimate agreement of 100.0%.

The successful testing demonstrated the safety and effectiveness of ORTHO VISION Max Analyzer when used to perform the ISXM test.