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:** December 18, 2020

4. **Device Name:**

   Trade Name or Proprietary name
   ORTHO Optix™ Reader

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

   Product Code:
   KSZ

5. **Predicate Device** The ORTHO Optix™ Reader, is substantially equivalent to the ORTHO VISION® Analyzer BK190338

6. **Registration Number:** The establishment number for the ORTHO Optix™ Reader is 2250051.

7. Device Description:

ORTHO Optix™ Reader is a bench top workstation that provides automated reaction grading, results interpretation and data management for ID-MTS™ Gel card Column Agglutination Technology.

Materials Provided with ORTHO Optix™ Reader:

- User Documentation
- ORTHO Optix™ Reader Software

Materials Required but not provided with ORTHO Optix™ Reader:

- Hand-held Barcode Scanner
- Reader Computer
- ID-MTS™ Gel Cards
- ORTHO Reagent Red Blood Cells
- Diluents
- Quality Control Reagents

ORTHO Optix™ Reader has been qualified for use with ID-MTS™ Gel cards, Ortho 0.8% Reagent Red Blood Cells, diluents, and quality control reagents. The following test types are supported by the ORTHO Optix™ Reader:

- Direct Agglutination tests: for example, ABO forward and reverse grouping, Rh typing and Rh phenotyping
- Direct Antiglobulin tests (DAT): for example, IgG DAT
- Indirect Antiglobulin tests (IAT): for example, antibody screening, antibody identification and IAT Crossmatch

8. Device Indications For Use:

The ORTHO Optix™ Reader is a system designed to automate reaction grading, results interpretation and data management when performing *in vitro* immunohematology testing of human blood utilizing ID-MTS Gel card technology. The ORTHO Optix™ Reader can be used as a standalone instrument or interfaced to the customer's Laboratory Information System (LIS).

9. Comparison to predicate device

Table 1 provides summary of the key features of the new device assessed against the predicate.

Table 1 Summary of Key Features of ORTHO Optix Reader vs. ORTHO VISION Analyzer (BK190338)

Similarities

Characteristic	New Device: (ORTHO Optix™ Reader)	Predicate Device: (ORTHO VISION® Analyzer BK190338)
Indications for Use	The ORTHO Optix™ Reader is a system designed to automate reaction grading, results interpretation and data management when performing *in vitro* immunohematology testing of human blood utilizing ID-MTS Gel card technology. The ORTHO Optix™ Reader can be used as a standalone instrument or interfaced to the customer's Laboratory Information System (LIS).	ORTHO VISION® Analyzer is an instrument designed to automate *in vitro* immunohematology testing of human blood utilizing ID-MTS gel card technology. ORTHO VISION® 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® Analyzer can be used as a standalone instrument or interfaced to the customer's Laboratory Information System (LIS).
Classification	Name: Automated blood grouping and antibody test system Device Class: II Product Code: KSZ Regulation Number: 21 CFR 864.9175	Same
Test Method	Column agglutination technology using ID-MTS Gel cards and reagents	Same

Characteristic	New Device: (ORTHO Optix™ Reader)	Predicate Device: (ORTHO VISION® Analyzer BK190338)
Testing:		
ABO and Rh Typing	X	Same
Antibody Screening	X	Same
Antibody detection	X	Same
Crossmatch	X	Same
Direct Antiglobulin	X	Same
Antigen testing	X	Same
QC testing	X	Same
Serial Dilutions for Titration Studies	X	Same
Specimen Types:		
Serum	X	Same
Plasma	X	Same
Red Blood Cells	X	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 • ISBT 128	Same

Characteristic	New Device: (ORTHO Optix™ Reader)	Predicate Device: (ORTHO VISION® Analyzer BK190338)
	• Code 128 • Code 3 of 9 • Code 2 of 5 (Interleaved)	
Laboratory Information System	Bidirectional	Same

Differences

Characteristic	New Device: (ORTHO Optix™ Reader)	Predicate Device: (ORTHO VISION® Analyzer BK190338)
Automation	Semi-automated: Automated result interpretation	Fully automated: Automated result interpretation, incubation, centrifugation, reagent handling, and metering
Incubator	Not applicable. No on-board incubator. Incubation is done external to ORTHO Optix™ Reader.	Includes on board incubators
Centrifuge	Not applicable. No on-board centrifuge. Centrifugation is done external to ORTHO Optix™ Reader.	Includes on board centrifuges
Metering	Not applicable. No on-board metering probe. Metering is done external to ORTHO Optix™ Reader.	Includes on board metering system
Sample, card, reagent, and waste storage	Not applicable. No on-board storage.	Includes on board storage

10. Non Clinical Performance Testing:

Numerous types of testing were performed for ORTHO Optix™ Reader including electromagnetic compatibility (EMC) testing, product safety testing, and software testing.

- Electrical and Safety Testing
  - Electromagnetic compatibility (EMC) testing according to FCC Part 15 Class A
  - Product safety testing according to IEC 61010

  ORTHO Optix™ Reader is in conformity to the standards tested.

- Software Testing

  System and software verification and validation activities included unit, integration, and system level software testing.

11. Clinical Performance Testing:

Performance Testing

Testing evaluated the agreement between the test system (ORTHO Optix™ Reader) results and the predicate system (ORTHO VISION® Analyzer) using ID- MTS Gel Cards. The validation was conducted at one internal site located at Ortho Clinical Diagnostics, Rochester NY and two external sites.

Overall concordance across three sites between ORTHO Optix™ Reader and the predicate met the acceptance criteria for the percent agreement one-sided 95% confidence interval lower bound of ≥ 99.0% for Direct Agglutination Tests and IAT Crossmatch, and ≥ 95.0% for Direct and Indirect Antiglobulin Tests.

The successful testing demonstrated the safety and effectiveness of ORTHO Optix™ Reader when used for the defined indications for use.