

9. 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. It has been confirmed that Optix Reader software version 2.0.3.50 is equivalent to the predicate software version 1.1.1.11.

Submitter

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Device

Proprietary and Established Name: ORTHO Optix™ Reader

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

Product Code: KSZ

Predicate Device

Proprietary and Established Name: ORTHO Optix™ Reader, BK220724, June 24, 2022

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
- ORTHO Sera Products
- Diluents
- Quality Control Reagents

ORTHO Optix™ Reader has been qualified for use with ID-MTS™ Gel cards, ORTHO 0.8% Reagent Red Blood Cells, ORTHO Sera Products, 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

Intended use / 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).

Comparison with Predicate

The following tables outline the similarities and differences between the modified ORTHO Optix™ Reader with software version 2.0 and the predicate device, ORTHO Optix™ Reader.

Similarities to Predicate

Characteristic	Predicate Device: (ORTHO Optix™ Reader BK220724 with software version 1.1.1.11)	Modified Device: (ORTHO Optix™ Reader with software version 2.0.3.50)
Indications for Use	The ORTHO Optix™ Reader is a system designed to automate reaction grading, results interpretation and data management when performing <i>in vitro</i> 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).	No change
Classification	II	No change
Product Code	KSZ	No change
Regulation number	864.9175	No change
Common name	Automated blood grouping and antibody test system	No change
Test Method	Column agglutination technology using ID- MTS Gel cards and reagents	No change

Characteristic	Predicate Device: (ORTHO Optix™ Reader BK220724 with software version 1.1.1.11)	Modified Device: (ORTHO Optix™ Reader with software version 2.0.3.50)
Testing:		
ABO and Rh Typing	Yes	No change
Antibody Screening	Yes	No change
Antibody detection	Yes	No change
Crossmatch	Yes	No change
Direct Antiglobulin	Yes	No change
Antigen testing	Yes	No change
QC testing	Yes	No change
Serial Dilutions for Titration Studies	Yes	No change
Specimen Types:		
Serum	Yes	No change
Plasma	Yes	No change
Red Blood Cells	Yes	No change
Reaction Grading	Digital image capture and analysis for reaction grading	No change
Result Interpretation	According to pre-defined rules as part of the software	No change
Image	High resolution color image	No change
Barcode Symbology's	<ul style="list-style-type: none"> • Codabar • ISBT 128 • Code 128 • Code 3 of 9 • Code 2 of 5 (Interleaved) 	No change

Characteristic	Predicate Device: (ORTHO Optix™ Reader BK220724 with software version 1.1.1.11)	Modified Device: (ORTHO Optix™ Reader with software version 2.0.3.50)
Laboratory Information System	Bidirectional	No change

Differences to Predicate

ORTHO Optix™ Reader software version 2.0 will introduce the following updated features:

Characteristic	Predicate Device: (ORTHO Optix™ Reader BK220724 with software version 1.1.1.11)	Modified Device: (ORTHO Optix™ Reader with software version 2.0.3.50)
Application Software (APSW)	The application software (APSW) module provides a Graphical User Interface and manages the workflow. The application software interfaces with the Lab Information System (LIS) for receiving orders and sending results. The application software is responsible for sending commands to the camera software.	The APSW module is reengineered to replace legacy software for reliability and maintainability.
Workflow for crossmatch tests	One donor per recipient at a time is allowed on a single crossmatch order.	Multiple donors per recipient can now be added to a single crossmatch order.
Workflow for patients	The current system only allows the user to process column images from one patient at a given time. The user must image the card for each order that uses the card.	Users can now process multiple tests on a single card without having to image the card for each order individually.
Enhanced workflow efficiency for Laboratory Information System (LIS) orders	Currently Donor Identification Numbers (DINs) are manually associated to patient crossmatch test.	The software now supports Laboratory Information System (LIS) orders which include Donor Identification Numbers (DINs) for patient crossmatch tests.
Enhanced workflow during review of quality control orders	Known expected Quality Control result not displayed, only the tested result.	Review of quality control orders will now display the known expected quality control results along with the tested result.
Enhanced workflow during association of reagents to orders	Reagent vial barcodes are scanned individually for lot and expiration date.	When using reagent lot tracking, it is no longer necessary to scan the barcode for each reagent vial. When multiple reagents are part of the same lot, one vial barcode is scanned, and the lot information is applied to all reagent vials for that test.

Nonclinical Testing

The following nonclinical testing was conducted to support substantial equivalence:

- Software verification and validation at unit, integration, and system levels. All acceptance criteria were met.
- System-level performance testing, including workflow, data handling, and LIS communication verification.
- Human factors and usability validation, including evaluation of critical tasks and risk mitigations.
- Method comparison testing between the modified device and the predicate device using the same ID-MTS™ Gel Cards, reagents, and samples. Testing covered all relevant column types using a matrix approach. All predefined acceptance criteria were met, including concordance and positive/negative percent agreement. No changes were made to the image processing algorithms; therefore, regression testing was sufficient to confirm unchanged performance. These nonclinical data demonstrate that the modified device performs as intended and supports substantial equivalence.

Clinical Testing

No clinical testing was required to support substantial equivalence. Nonclinical testing was sufficient to demonstrate safety, effectiveness, and performance of the modified device.

Performance Data

Studies were performed to document the performance characteristics and the substantial equivalence of the candidate device to the predicate device. These studies included:

- System and software verification and validation activities which encompassed unit, integration, and system level software testing.
- Summative human factors validation conducted to evaluate critical tasks and verify the effectiveness of implemented risk mitigations.
- Method comparison testing, performed internally at Ortho-Clinical Diagnostics Inc., comparing the ORTHO Optix™ Reader with the candidate software version to the ORTHO Optix™ Reader with the predicate software version. To efficiently assess all column types, a matrix approach was used to select tests and cards covering all red blood cell reagents and column types. The same ID-MTS™ Gel Cards and reagents were tested on both software versions using the same samples. The following acceptance criteria (concordance at the one-sided lower 95% confidence bound) were applied, and all test results met these criteria:
 - Direct Agglutination Tests – 99.4% or greater
 - Direct and Indirect Antiglobulin Tests – 98.0% or greater
 - IAT Crossmatch Test - 99% or greater

Conclusion

The testing demonstrated equivalent performance of the ORTHO Optix™ Reader with software version 2.0.3.50 versus the predicate ORTHO Optix™ Reader with software version 1.1.1.11 (BK220724) when used for the defined indications for use. In addition to method comparison performance testing, software verification and validation, system-level testing, and usability validation were completed and met all predefined acceptance criteria. No clinical testing was required, as the nonclinical evidence was sufficient to support safety and effectiveness.

Collectively, the data demonstrates that the modified device is as safe, as effective, and performs as well as the predicate device, and that the modifications do not raise new questions of safety or effectiveness.