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:**

   Ortho-Clinical Diagnostics, Inc.
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2. **Contact Person and Address:**

   Samy Puccio Director of Regulatory Affairs
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3. **Preparation Date:** April 04 , 2022

4. **Device Names**:

   Trade Name or Proprietary name
   ORTHO Optix™ Reader with Sera Product

   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

Characteristic	New Device: (ORTHO Optix™ Reader)	Predicate Device: (ORTHO VISION® Analyzer BK190338)
Barcode Symbologies	• Codabar • ISBT 128 • Code 128 • Code 3 of 9 • Code 2 of 5 (Interleaved)	Same
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:

All testing performed and submitted with the original Optix Reader 510(k), BK200549, is applicable to this submission for review of the modified device, which is the addition of the ORTHO Sera products to the Optix Reader..

Performance validation was performed to add the ORTHO Sera onto the ORTHO Optix Reader test menu at two external sites and one internal site. The test strategy is based on a matrix approach as described and agreed in Pre-Sub Supplement BQ180264/2 (Refer to Section 7.0), where four representative ORTHO Sera were selected to migrate all thirteen ORTHO Sera onto ORTHO Optix Reader. A matrix approach is an appropriate test strategy for the ORTHO Optix Reader based on the follow points:

- The ORTHO Sera identified in Table 2 below are approved for use on the ORTHO VISION Analyzer (predicate device).
- The ORTHO Optix Reader has leveraged the ORTHO VISION Analyzer Imaging Process System (reader module) for reading of the ID-MTS Gel Cards (cards).
- The ORTHO Optix Reader does not automate the ORTHO Sera test procedure described in the ORTHO Sera IFU with the exception of the reading of the cards.
- The performance validation described in previous Pre-Sub BQ180264 is expected to confirm the reading of the representative cards for each column type across all reaction grades is concordant for ORTHO Optix Reader and the ORTHO VISION Analyzer.
- The ORTHO Sera study focused on the card types (Buffered gel card and Anti-IgG gel card), special reagents (Papain), and test types (Direct Agglutination and Indirect Antiglobulin) utilized by the thirteen ORTHO Sera assays identified in the Table 2 below.

Table 2: ORTHO Sera Products

ORTHO Sera Products
Anti-Fya (Monoclonal) (IgG) Anti-Fyb ORTHO™ Sera
Anti-S (Monoclonal) (IgG) Anti-s (Monoclonal) (IgG) ORTHO™ Sera
Anti-Jka (Monoclonal) Anti-Jkb (Monoclonal) ORTHO™ Sera
Anti-D (IAT) (Monoclonal Blend) ORTHO™ Sera
Anti-K (Monoclonal) ORTHO™ Sera
Anti-P1 (Murine Monoclonal) ORTHO™ Sera
Anti-Lea (Murine Monoclonal) Anti-Leb (Murine Monoclonal) ORTHO™ Sera
Anti-N (Murine Monoclonal) (IgG) ORTHO™ Sera
Anti-D (DVI) (Monoclonal) ORTHO™ Sera

*Note: bolded ORTHO Sera products are selected as representative assays

External **Performance Validation Plan**

The performance validation of the ORTHO Sera used the matrix approach test strategy in which four (4) representative ORTHO™ Sera assays (Anti-D (IAT), Anti-S, Anti-Jka, and Anti-D (DVI) were selected for testing to migrate all thirteen (13) ORTHO Sera assays onto ORTHO Optix Reader. The study was conducted at two external sites and one internal site.

The sample size for testing was driven by a number of factors. First, Per FDA feedback (BQ180264/Supplement 2), the Direct Agglutination Antigen tests per each card type must exhibit a percent agreement result where the lower limit of a one sided 95% confidence interval is ≥ 95.0%. The minimum sample sizes required for a corresponding number of allowable failures to meet the requirement was calculated using the Binomial Exact Confidence Interval. These values aided in determining the appropriate sample size for testing.

Second, Per FDA feedback (BQ180264/Supplement 2), Indirect Antiglobulin tests must exhibit a percent agreement result where the lower limit of a one sided 95% confidence interval is ≥ 95.0%. The minimum sample sizes required for a corresponding number of allowable failures to meet the requirement was calculated using the Binomial Exact Confidence Interval. These values aided in determining the appropriate sample size for testing.

Attempts were also made to include samples with weak hemagglutination reactions for testing.

A total of 2,293 test results from 861 individual unique samples were successfully read on the ORTHO Optix™ Reader, representing a total of 2,293 microtubes. Samples represented diverse population groups from various geographic areas and were composed of samples sourced through the sites and sample vendors, representing hospital in-patient and out-patient populations and blood donors.

The performance validation consisted of a method comparison testing conducted at three sites:

Site Name	Location	Type of Site and Services	Prinicipal Investigator
Bloodworks Northwest - Renton	701 SW 39th Street, Renton, WA 98057	Donor Testing Lab	Ashley Rose
Bloodworks Northwest - Seattle	921 Terry Ave., Seattle, WA 98104	Transfusion Services Lab	Dr. Theresa Nester
Ortho-Clinical Diagnostics	130 Indigo Creek Drive, Rochester, NY 14626	Internal Site	Roberta Parente

APPROACH

A matrix approach test strategy was used for the study in which four (4) representative ORTHO Sera assays (Anti-Jka, Anti-DVI, Anti-D (IAT) and Anti-S, and) were selected for testing to migrate all thirteen (13) ORTHO™ Sera assays onto ORTHO Optix™ Reader. The study focused on the card types (Buffered gel card and Anti-IgG gel card), special reagents (Papain), and test types (Direct Agglutination and Indirect Antiglobulin) utilized by the thirteen ORTHO Sera assays.

- ORTHO Sera Anti-Jka (Direct Agglutination) is selected for testing as a representative assay for those sera that use Buffered Gel cards and Papain as enhancement in the test protocol. This sera is selected to confirm that ORTHO Optix Reader reads cards equivalent to ORTHO VISION Analyzer (predicate) with the additional fluid volume from Papain. This assay represents the following:

    - Anti-Jkb (Monoclonal)
    - Anti-Lea (Murine Monoclonal)
    - Anti-Leb (Murine Monoclonal)

- ORTHO Sera Anti-D (DVI) (Direct Agglutination) is selected as a representative assay for those sera that use Buffered Gel cards in the test protocol and this assay is anticipated to be used more frequently by customers. This assay represents the following:

    - Anti-N (Murine Monoclonal) (IgG)
    - Anti-K (Monoclonal)

- ORTHO Sera Anti-D (IAT) (Indirect Antiglobulin) is selected as a representative assay
- for those sera that use Anti-IgG Gel cards in the test protocol and this assay is anticipated to be used more frequently by customers. This assay represents the following:

    - Anti-P1 (Murine Monoclonal)
    - Anti-Fya (Monoclonal) (IgG)
    - Anti-Fyb

- ORTHO Sera Anti-S (Indirect Antiglobulin) is selected as a representative assay for those sera that use Anti-IgG Gel cards in the test protocol and this antigen is present/absent on the red cell surface relatively evenly within the population. This sera is selected to target an even distribution of positive and negative reactions based on a random sample population. This assay represents the following:

    - Anti-s (Monoclonal) (IgG)

TEST METHOD

Random Samples will be used for this study. Sample size and acceptance criteria are presented in Tables 3 and 4.

Buffered Gel Cards (Direct Agglutination)

Table 3. Validation Testing of ORTHO Sera Tests performed/read on the ORTHO VISION Analyzer Compared to the Same Gel Cards Read on the ORTHO Optix Reader

Test Characterization	Test Type	Test or Test Method	Total Sample Size	Acceptance Criteria Applied to: Overall Agreement by Card Type	Concordance Acceptance Criteria (lower 95% CI)
Direct Agglutination Testing	Antigen Typing	Anti-Jka Anti-D (DVI)	1253	1253 100%	) 95%

Anti-IgG Gel Cards (Indirect Antiglobulin)

Table 4. Validation Testing of ORTHO Sera Tests performed/read on the ORTHO VISION Analyzer Compared to the Same Gel Cards Read on the ORTHO Optix Reader

Test Characterization	Test Type	Test or Test Method	Total Sample Size	Acceptance Criteria Applied to: Overall Agreement by Card Type	Concordance Acceptance Criteria (lower 95% CI)
Indirect Antiglobulin Testing (960 total columns)	Antigen Typing	Anti-D(IAT) Anti-S	1040	1039 99.9%	95%

Samples were processed and read on the ORTHO VISION Analyzer. The cards were removed from the analyzer and immediately re-read on the ORTHO Optix Reader. Agreement between the test system (ORTHO Optix Reader) results and the comparative system (ORTHO VISION Analyzer) using cards was assessed. Discordant results and results of investigative testing were also reviewed cross-functionally. All unexpected errors are listed and had no effect on the method comparison results used to evaluate system performance. See D54396 Attachment 68

Method Comparison Concordance Analysis was performed and included only valid test results from the ORTHO Optix™ Reader and the ORTHO VISION® Analyzer.

DATA ANALYSIS AND ACCEPTANCE CRITERIA

Results were assessed on a microtube by microtube basis using a paired sample comparison

between the predicate device (ORTHO VISION® Analyzer) and the test device under evaluation (ORTHO Optix™ Reader). For microtube reaction grades to be concordant between devices either both results had to be negative or both had to be positive (any reaction grade 1+ through 4+).
The percent agreement (concordance) was analyzed using the following equation:

Percent Agreement = 100% x (a+d) / (a+b+c+d)

A = True Positive; B = False Positive; C = False Negative; D = True Negative

Concordance analysis was performed as specified in D54395, ORTHO Sera on ORTHO Optix Reader External System Performance Validation Test Plan for MTS Gel Cards. Specified analyses were designed to satisfy the following criteria:

FDA Criteria: Acceptance criteria are documented in SP01097 ORTHO Optix Reader PreSub Supplement dated 07/07/2020 and the subsequent written feedback to FDA (BQ180264/Supplement 2) dated 09/08/2020 (Accepted criteria indicated in tables 3 and 4 above).

The ORTHO Optix Reader shall demonstrate concordance with the ORTHO VISION Analyzer (predicate method) at the one-sided lower 95% confidence limit as follows:

• Concordance between the ORTHO VISION Analyzer and the ORTHO Optix Reader for Direct Agglutination Tests: the one sided lower 95% confidence limit should be ≥ 95.0%.
• Concordance between the ORTHO VISION Analyzer and the ORTHO Optix Reader for Indirect Antiglobulin Tests: the one sided lower 95% confidence limit should be ≥ 95.0%.

The acceptance criteria were only applied to the combined site data to support statistical analysis and per D54395 (Test Plan).

Electrical **Safety and EMC Evaluation**

Ortho Clinical Inc. update regarding the Electrical Safety and EMC evaluation was addressed in the Amendment dated Feb 04, 2021 (in response to FDA request for information for Ortho 510k BK200549) Attachment 73.

Electrical Safety and EMC testing information was included with ORTHO 510(k) BK200549. No new testing was performed for this modified submission. The information below for Electrical Safety and EMC is provided for reference.

ELECTRICAL SAFETY

Product safety testing demonstrated compliance to global product safety related standards for in vitro diagnostics medical equipment, CSA/UL/EN/IEC 61010-1:2010 +A1:2016, and 61010-2-101:2015, performed by ETL a Nationally Recognized Test Laboratory (NRTL).
Conformity will be documented through the NRTL's issuance of a CB Scheme Report, including a CB Test Certificate and IEC informative report.

North American conformity is documented through ETL's issuance of a Listing Report and the addition of the appropriate Agency marking on the units dataplate.

EMC
EMC testing to IEC/EN 61326-1:2012 and 61326-2-6:2013, with a computer system for support, demonstrated compliance to European EMC requirements will be performed and documented by TUV Rheinland.

Emissions testing to FCC standards (FCC Part 15 Class A), with a computer system for support, demonstrated compliance to North American requirements will be performed and documented by TUV Rheinland.

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.