510(k) –Summary

As Required by Sec 807.92(c)

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Device Trade/Proprietary Name: ORTHO CONNECT™ 3.0

Device Common/Usual Name: Automated Blood Grouping Antibody Test System

Product Code: KSZ

Regulatory Class: Class II

Predicate Device: **BK160124:** Ortho Connect Version 2.0 (STRATEC Biomedical UK Limited, Centrum Point, Third Avenue, Centrum 100, Burton upon Trent Staffordshire, DE14 2WD, United Kingdom)

Device Description:
ORTHO CONNECT™ 3.0 is a middleware solution based on the ORTHO CONNECT™ 2.0 and designed for use within Blood Establishments to collect data from blood grouping immunohematology tests, which allows operators to track individual patient and donor samples and link them to the appropriate test results. The ORTHO CONNECT system communicates via an American Society for Testing and Materials (ASTM) interface with the Laboratory Information Management System (LIMS) and Ortho blood typing instruments. The software organizes worklists and receives results from the analyser instrumentation.

Substantially Equivalent Devices
STRATEC Biomedical UK Limited believes ORTHO CONNECT™ 3.0 to be substantially equivalent to the following predicate device currently in interstate commerce, with respect to comparable features and intended use:

- Product Name: ORTHO CONNECT™ 2.0
- Product Code: KSZ
- 510(k) Number: BK160124

ORTHO CONNECT™ 3.0 Software Device Description – New Functionality:
ORTHO CONNECT™ 3.0 is based on ORTHO CONNECT™ 2.0 from STRATEC Biomedical UK Limited. STRATEC has updated their software to encompass the requirements of ORTHO CONNECT™3.0. The software is designed to run on a Master Server PC and accessed through a web browser on a Local Area Network or intranet. See further details in section 'Device Description'.

Device Description – Existing Functionality:
ORTHO CONNECT™ 3.0 encompasses the core functionality of ORTHO CONNECT™2.0 software.

Intended Use/ Indications for Use:

ORTHO CONNECT™ Software is designed to collect data from the Ortho Clinical Diagnostics blood typing instruments and its proprietary immunohematology reagent system, which allows operators to track individual patient and donor samples and link them to the appropriate test results. The software collates the results from testing, assigns outcomes to individual samples according to configured rules, and formats output files that can be sent to a Laboratory Information Management System (LIMS).

ORTHO CONNECT™ Software is intended to be used by Blood Establishments and by personnel who are trained in its operation.

Functional Characteristics:
ORTHO CONNECT™ v3.0 Software is functionally similar to ORTHO CONNECT™ v2.0 Software and is based on Aurora Enterprise. This is summarized in Table 1 and Table 2, respectively.

Table 1: Similarities between the Ortho Connect 3.0 and Predicate Device

Characteristic	ORTHO CONNECT™ v2.0 (Predicate Device)	ORTHO CONNECT™ v3.0 (Candidate Device)
Intended Use/Indication for Use	ORTHO CONNECT™ Software is designed to collect data from the Ortho Clinical Diagnostics ORTHO VISION™ Analyzer and its proprietary Immunohematology reagent system, which allows operators to track individual patient and donor samples and link them to the appropriate test results. The software collates the results from testing, assigns outcomes to individual samples according to configured rules, and formats output files that can be sent to a Laboratory Information Management System (LIMS). ORTHO CONNECT™ Software is intended to be used by Blood Establishments and by personnel who are trained in its operation.	ORTHO CONNECT™ Software is designed to collect data from the Ortho Clinical Diagnostics blood typing instruments and its proprietary Immunohematology reagent system, which allows operators to track individual patient and donor samples and link them to the appropriate test results. The software collates the results from testing, assigns outcomes to individual samples according to configured rules, and formats output files that can be sent to a Laboratory Information Management System (LIMS). ORTHO CONNECT™ Software is intended to be used by Blood Establishments and by personnel who are trained in its operation. .

Characteristic	ORTHO CONNECT™ v2.0 (Predicate Device)	ORTHO CONNECT™ v3.0 (Candidate Device)	Comments
Software only product	Yes	Yes	Both the predicate and candidate devices are software-only products.
Blood Establishment Computer System (BECS)	Yes	Yes	Both the predicate and candidate devices are intended for, but not limited to, use as BECS.
IBM-compatible PC independent	Yes	Yes	The predicate candidate device runs on Windows 10 Operating Systems. The candidate device also runs on Windows 10. Both run on windows server 2016.
Sample Result Database	Yes	Yes	Relational Database Management System (RDBMS) methodology is utilised, which is an industry standard approach.
Manual Entry	Yes	Yes	The manual Entry option allows for manual (keyboard) entry of data for situations where the data is not available via electronic means from an LIS or an Instrument.
Workflow Controller	Yes	Yes	The Workflow Controller runs in the background and controls process steps to move samples through the worklist according to set configurations. It also scans for Laboratory Information System (LIS) and Instrument Files as part of the process.

Characteristic	ORTHO CONNECT™ v2.0 (Predicate Device)	ORTHO CONNECT™ v3.0 (Candidate Device)	Comments
Result Approval	Yes	Yes	Based on configuration settings, both the predicate and candidate device provided a user approval step prior to release of results (export) to the LIS. The sample results may also be rejected or re-order during this step.
Reporting	Yes	Yes	The Reporting option allows the user to select and print reports. Includes sample searching and filtering capabilities
Search and View	Yes	Yes	Search & View features allow the user to recall and view full sample orders and result information using a variety of search options such as date, barcode ID, etc
User Login	Yes	Yes	The software is fully user/password controlled. Users have restricted access to menu's/functions. System Manager\Administrator can control password style/policy (e.g. must have at least one Uppercase letter, a number and a special symbol £$!&@ etc) and expiration.
Rules Engine	Yes	Yes	The Rules Engine is a configurable feature in the software. This allows the predicate and candidate device to set-up certain conditions about patient orders and result outcomes through which, these are checked and acted upon. Rules may be applied to incoming orders, results, and final release conclusions.
Configuration Settings – Instrument Devices	Yes	Yes	Both the predicate and candidate device allow for instruments to be defined on the system. Once the instruments have been entered onto the system, ORTHO CONNECT™ can be set up to monitor and process files from these instruments.
Configuration Settings – LIS (LIMS) Devices	Yes	Yes	Both the predicate and candidate device allow for LIS to be defined on the system. Once configured the software will monitor for incoming orders and export result at the completion of the testing process.
Customize Worklist	Yes	Yes	The user can customise the worklist display so that details can be displayed in user preferred/optimum order.

Characteristic	ORTHO CONNECT™ v2.0 (Predicate Device)	ORTHO CONNECT™ v3.0 (Candidate Device)	Comments
Security Access	Yes	Yes	Users with the appropriate security access can control user access credentials of other users. The software is fully user/password controlled. Security access can be restricted to a screen or functions within the screen. Users with the appropriate security access can control password style and expiration.
View Audit Log	Yes	Yes	Secure level option that allows the user activity log to be viewed.
Remote Review	Yes	Yes	Remote access within the hospital network to the main ORTHO CONNECT™ system to review and approval (reject) results.
View Image	Yes	Yes	Result Image can be viewed and taken into account as part of the final result approval and upload authorization
Software Translation	Yes	Yes	Both software can be translated to regional requirements.
Multi Device Support	Yes	Yes	Devices can be located in different physical locations but within the same hospital network

Table 2: Differences between the Ortho Connect 3.0 and Predicate Device

Characteristic	ORTHO CONNECT™ v2.0 (Predicate Device)	ORTHO CONNECT™ v3.0 (Candidate Device)	Comments
System Settings	Yes	No	A user with the appropriate security access can administer functions associated with management of the software. The same system settings are available within both the predicate and candidate device. Within the predicate device, a system settings menu was established. However this menu has now been removed within the candidate device and all of the features that were present within the system settings menu, are accessible within a different menu structure.
Microsoft Windows Graphical User Interface	Yes	No	The predicate device employ a Windows-based Graphical User Interface (GUI). But the candidate device is accessed via a browser based GUI.
SQL Server Version.	Yes	No	The predicate device uses SQL 2008. The candidate device utilizes SQL 2016.
Web Browser Access (Key feature)	No	Yes	The candidate device may remotely access the software on the master installation from a web browser within the facility.
Multiple Databases	Yes	No	The predicate device allows for multiple databases with secured accessed assigned to individuals with the correct user level security permissions. The candidate device employs a single database with secured access to individuals with the correct user level security permissions for processing and storing results.

Characteristic	ORTHO CONNECT™ v2.0 (Predicate Device)	ORTHO CONNECT™ v3.0 (Candidate Device)	Comments
Manager – Database Management	Yes	No	For the predicate device, there is an option that allows the user to administer multiple databases used by the software. This feature is not present within the candidate device due to the presence of only one working database.
Manager – Database Locking	Yes	No	For the predicate device, databases can be secured and access assigned to individuals with the correct user level security permissions. This feature is not required within the candidate device as it does not use multiple working databases.
On-line Help	Yes	No	The predicate device includes screens or selecting a help button. The candidate device is supplied with a user manual in electronic format.
Configuration - Reports	Yes	No	The predicate device includes a menu driven option to allow the user to define custom reports. The candidate device includes a library of pre-configured reports to address the reporting needs of the testing laboratory.

SAFETY AND EFFECTIVENESS DATA

The ORTHO CONNECT software was tested and validated using established procedures for software development that encompasses design through software testing. Testing was performed utilising unit testing and system level testing. Completed systems were tested and validated. The results of testing demonstrate that ORTHO CONNECT meets the requirements of the intended use.

Testing

System Integration testing of ORTHO CONNECT was performed in a User facility (Ortho Clinical Diagnostics Inc.). The conclusion from testing demonstrates that ORTHO CONNECT meets its specifications and

functions as expected within its intended use. The conclusion from testing demonstrates that ORTHO CONNECT meets its specifications and functions as expected within its intended use. A summary of the test records are contained in section **031_Appendix 10 System Validation** of the 510(k) application.

Other Information

Similarities and Differences of the Predicate Device

Ortho Connect 2.0 was chosen as the predicate devices because of the close similarity to the functionality provided by Ortho Connect 3.0. Both are computer systems capable of receiving data from various instruments, performing data assessment on this data and exporting the data in file format. Minor differences do exist between the predicate device (Ortho Connect 2.0) and Ortho Connect 3.0, however, these are limited to additional functionality areas which do not affect the safety and effectiveness of core functionality.

Conclusion

Based on 21 CFR part 807.100 5b 2(i) regulation, STRATEC proposes that ORTHO CONNECT™ 3.0 Software is substantially equivalent to predicate ORTHO CONNECT™ 2.0.

In summary, the intended use, technological characteristics and functionality of the ORTHO CONNECT™ Software as compared to the predicate device do not raise any new types of safety or effectiveness questions. Like its predicate device, ORTHO CONNECT™ Software is a fully validated system that is safe and effective for its intended use.

Performance Testing

Software Functional Tests have been written to test each function of the Ortho Connect 3.0 Software, a selection of summaries can be found in **Appendix 8**. A summary of failures can be found in **section 16K of document 016_software**.

Regression testing to ensure that changes made have not impacted on other areas of the software, and validation testing to prove full end-to-end functionality of the software, are performed formally before release of the software. The system validation of Ortho Connect 3.0 Software is included in **Appendix 10.**

Automation Testing - Automated test scripts are designed to allow swift execution of test scenarios. These will be utilised as part of the formal verification and validation (V&V) of the software. For the Ortho Connect 3.0 project, automation will be used for the Verification & Validation stage of testing only. This will be in the form of tests that are executed that cover the requirements for a given section. A Validation Test Protocol will also be created that will test all Product Requirements (PRQs) for the Ortho Connect Product. Any requirements that cannot be covered by automation for the V&V stage will be covered by a manual Software Functional Specification test document. See **Appendix 08** for further information.