

510(k) – Summary

As Required by Sec 807.92(c)

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Device Trade/Proprietary Name: ORTHO CONNECT™

Device Common/Usual Name: Blood Establishment Computer Software

Product Code: 81MMH

Predicate Device: **BK090061:** Sanguin Aurora Version 2.0
(STRATEC Biomedical UK Limited, 1 Barberry Court,
Callister Way, Burton – upon – Trent, Staffordshire, DE14
2UE, England, U.K.)

Device Description:

ORTHO CONNECT™ Software Device Description – New Functionality:

ORTHO CONNECT™ is based on the Aurora Software from STRATEC Biomedical UK Limited. STRATEC has enhanced (refer to “Table 2: Addition to the Ortho Connect Software” for detail) their software to encompass the requirements of ORTHO CONNECT. The software is designed to run on a Local Area Network, with access to networked instrument folders. Communication with instruments is to be file based using ASTM. Software will run with SQL server installed locally on the PC running the Aurora OCD Blood Grouping application.

Device Description – Existing Functionality:

ORTHO CONNECT™ inherits the structure and core functionality of Sanguin Aurora 2.0 software. This core provides essential base functions including database, secure login, audit trails, data recall and print functions.

The facility to handle multiple assays per sample is derived by configuration of the existing functionality inherited from Sanguin Aurora 2.0. On detection of user configured trigger results the software can request additional testing based on other assays/analytes and hold the initial sample until all testing is complete and a conclusion has been reached. Before those final results are accepted, privileged user authorisation is required.

Intended Use/ Indications for Use:

ORTHO CONNECT™ Software is designed to collect data from blood grouping and immunology assays, which allows operators to track individual patient and donor samples and link them to the appropriate test results. The software collates the results of testing, assigns outcomes to individual samples according to a configured rule, 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 Establishment and Clinical Diagnostic Laboratory personnel who are trained in its operation.

Technological Characteristics:

ORTHO CONNECT™ Software is technologically similar to Aurora v2.0. Software is summarized in Table 1 and Table 2, respectively.

Table 1: Similarities between the Ortho Connect and Predicate Device

Characteristic	Sanguin Aurora Version 2.0 (Predicate Device)	ORTHO CONNECT™ (Submitted Device)
Product Code	81MMH	81MMH
Intended Use/Indication for Use	Sanguin Aurora 2.0 is indicated for use is in Clinical Diagnostic Laboratories, Blood Bank and Blood Establishments where it captures test and result data from laboratory equipment. It can be applied to single tests or a panel of tests that are used to screen blood donations (whole blood or plasma) as a pre-requisite to transfusion. Typically these tests would include viral markers such as Hepatitis Markers and HIV and may include non-viral testing such as ABO and Rhesus confirmation of donors, patient typing and antibody screening.	ORTHO CONNECT™ Software is designed to collect data from blood grouping and immunology assays, which allows operators to track individual patient and donor samples and link them to the appropriate test results. The software collates the results of testing, assigns outcomes to individual samples according to a configured rule, 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 Establishment and Clinical Diagnostic Laboratory personnel who are trained in its operation.
Software-only product	Yes	Yes
Blood Establishment Computer System (BECS)	Yes	Yes
IBM-compatible PC independent	Yes	Yes
Microsoft Windows Graphical User Interface	Yes	Yes
Open database connectivity (ODBC)	Yes	Yes
Sample Result Database	Yes	Yes
Help text is available	Yes	Yes
Main – Enter	Yes	Yes
Main – Monitor	Yes	Yes
Main – Reporting	Yes	Yes
Main – Search & View	Yes	Yes
Main – User Login	Yes	Yes
Main – Validate	Yes	Yes
Configuration – Assay	Yes	Yes
Configuration – Devices	Yes	Yes
Configuration – Report	Yes	Yes
Configuration – Utilities	Yes	Yes
Configuration – Validate	Yes	Yes

Characteristic	Sanguin Aurora Version 2.0 (Predicate Device)	ORTHO CONNECT™ (Submitted Device)
Configuration – Worklist	Yes	Yes
Manager – Database Management	Yes	Yes
Manager – Database Locking	Yes	Yes
Manager – Security Access	Yes	Yes
Manager – System Settings	Yes	Yes
Manager – Translation Utility	Yes	Yes
Manager – View Log	Yes	Yes
Multi Device Support	Yes	Yes
Remote Review	Yes	Yes

Table 2: Addition to the Ortho Connect Software

Characteristic	Sanguin Aurora Version 2.0 (Predicate Device)	ORTHO CONNECT™ (Submitted Device)
View Image	No	Yes

The detailed information for the similarities/differences in Functionality is available in section 012_Substantial Equivalence statement.

Based on an assessment of relevant technological characteristics, ORTHO CONNECT™ Software substantially equivalent to Sanguin Aurora Version 2.0 Software.

SAFETY AND EFFECTIVENESS DATA

The ORTHO CONNECT software was developed 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. Each Rule was evaluated, and any potential changes to the Rules were assessed for necessary regression testing. 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. A summary of the test records are contained in section 036_ Appendix 15 Verification and Validation Testing Summary Report of the 510(k) application.

Other Information

Not Applicable

Conclusion

Based on 21 CFR part 807.100 5b 2(i) regulation, STRATEC proposes that ORTHO CONNECT™ Software is technologically similar to predicate Sanguin Aurora v2.0. It utilizes the same software architecture and is operated on the Aurora 2.0 database.

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 and are substantially equivalent. Like its predicate device, ORTHO CONNECT™ Software is safe and effective for its intended use.