

510(k) – Summary

As Required by Sec 807.92(c)

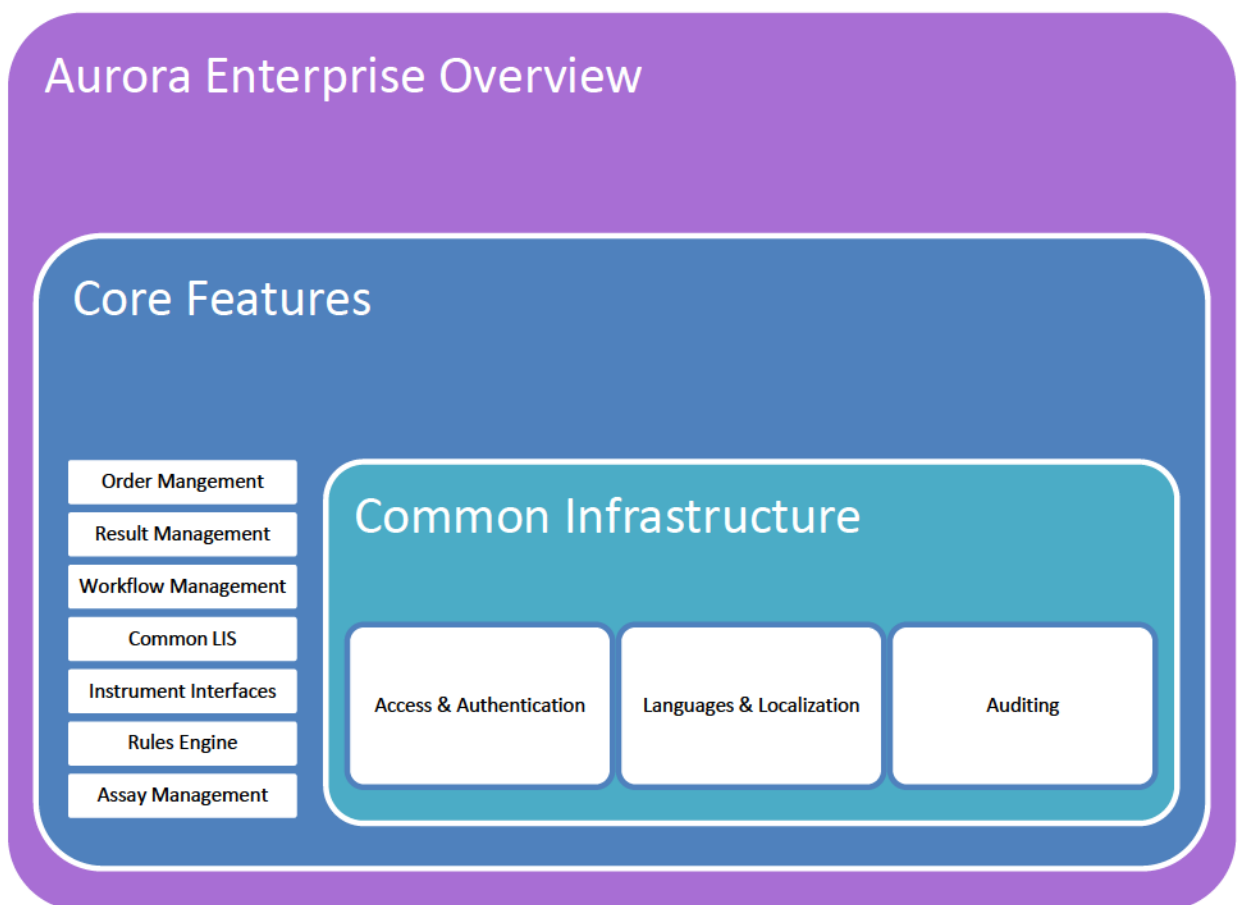
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		Establishment Registration Number	3003966680
Date Prepared:	25 Sept 2017		
Device Trade/Proprietary Name:	Aurora Enterprise		
Device Common/Usual Name:	Blood Establishment Computer Software		
Product Code:	MMH		
Predicate Device:	BK090061: Sanguin Aurora Version 2.0 (STRATEC Biomedical UK Limited, Centrum point, Centrum 100, Burton – upon – Trent, Staffordshire, DE14 2WD, England, U.K.)		

Device Description:

The candidate device, Aurora Enterprise, software consists of a core system providing essential basic functionality including database, secure login, audit trails, data recall and print functions designed for collating laboratory result data. Attached to the core system are the application modules. Application modules control which assay and instrument types are available to the installation; any combination of modules may be used dependent on the customer's requirements. The base system provides the central framework from which all the applications are performed.

The solution is module based which allows for the addition of interfaces or modules without having to uninstall or re-install the existing software. Figure 1 presents a high-level overview of Aurora Enterprise Software,

Figure 1: Aurora Enterprise Software



The software is designed to collect data of assays from instruments, which allow operators to track clinical samples and link them to the appropriate test results. The software collates the results of testing, assigns outcomes to samples according to a testing algorithm, and formats output files that can be sent to a Laboratory Information

System (LIS).

The software offers a comprehensive central data review point prior to final result release. Functionality is highly configurable, but within a controlled environment achieved by extensive use of menu options. This gives maximum opportunity for the user, with the appropriate security access, to shape and optimise the flow of data through the system while still keeping within defined boundaries.

The software can receive and process sample and result data; where instrumentation is capable of performing its own data processing, such as, NAT/PCR based assays, the instrument will have already qualified the data and then converted the 'raw values' into manageable results. Data is received from these instruments in the form of finished results with no requirement of the external software package to perform data processing.

Export and Accept of final results can be controlled via menu options or locked down to be processed according to user defined options.

Intended Use:

Aurora Enterprise is a computer software product for use within Blood Establishments and Clinical Diagnostic Laboratories which enables communication between Laboratory Information Systems and Laboratory Instrumentation. The software product is designed to capture and collate data provided by laboratory instrumentation, where the instrumentation is capable of performing its own data processing, having qualified the data and converted the 'raw values' into interpreted results. The software collects data of assays from instruments, which allow operators to track patient samples and link them to the appropriate test results. The software collates the results of testing, and formats output files that can be sent to a Laboratory Information System (LIS). In addition, rules may be configured to determine a final result outcome prior to formatting output files for export to an LIS. The software allows for manual entry of results. Typical tests would include those that are used to screen blood donations (whole blood or plasma) as a pre-requisite to transfusion such as viral markers tested by NAT/PCR and Immunoassay. The software has the capability to send worklists to instruments from orders it receives from an LIS, or manually entered, but takes no control over any instrument operation.

Aurora Enterprise is intended for use by Blood Establishment and Clinical Diagnostic laboratory personnel who are trained in its operation.

Technological Characteristics:

The similarities and differences between the technological characteristics for the predicate device Sanguin Aurora version 2.0 Software and the Aurora Enterprise

Software are summarized in Table 1 and Table 2, respectively.

Table 1: Similarities between the Aurora Enterprise and Predicate Device

Characteristic	Sanguin Aurora Version 2.0 (Predicate Device)	Aurora Enterprise (Submitted Device)
Product Code and Classification Name	81MMH	MMH
Intended Use	Sanguin Aurora 2.0 is indicated for use 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.	Aurora Enterprise is a computer software product for use within Blood Establishments and Clinical Diagnostic Laboratories which enables communication between Laboratory Information Systems and Laboratory Instrumentation. The software product is designed to capture and collate data provided by laboratory instrumentation, where the instrumentation is capable of performing its own data processing, having qualified the data and converted the 'raw values' into interpreted results. Typical tests would include those that are used to screen blood donations (whole blood or plasma) as a pre-requisite to transfusion such as viral markers tested by NAT/PCR, Immunoassay, and non-viral testing such as ABO and Rhesus confirmation of donors, patient typing and antibody screening.
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

Table 2: Differences between the Aurora Enterprise Software and Predicate Device

Characteristic	Sanguin Aurora Version 2.0 (Predicate Device)	Aurora Enterprise (Submitted Device)
Pooling Management	Yes	No

Based on an assessment of relevant technological characteristics, Aurora Enterprise software substantially equivalent to Sanguin Aurora Version 2.0 Software. The full table of substantial equivalence can be found in Section 12.

Non-Clinical Performance Evaluation

Analysis of non-clinical performance data was not relied on to support the determination of substantial equivalence between the Aurora Enterprise Software and predicate device Sanguin Aurora Version 2.0 Software.

Clinical Performance Evaluation

Analysis of clinical performance data was not relied on to support the determination of substantial equivalence between the Aurora Enterprise Software and predicate device Sanguin Aurora Version 2.0 Software.

Other Information

Not Applicable

Conclusion

Based on analysis of the relevant technological characteristics, the Aurora Enterprise Software is substantially equivalent to predicate Sanguin Aurora Version 2.0 Software.

In summary, the intended use, technological characteristics, and functionality of the Aurora Enterprise 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, Aurora Enterprise Software is safe and effective for its intended use.