

510(k) – Summary

As Required by Sec 807.92(c)

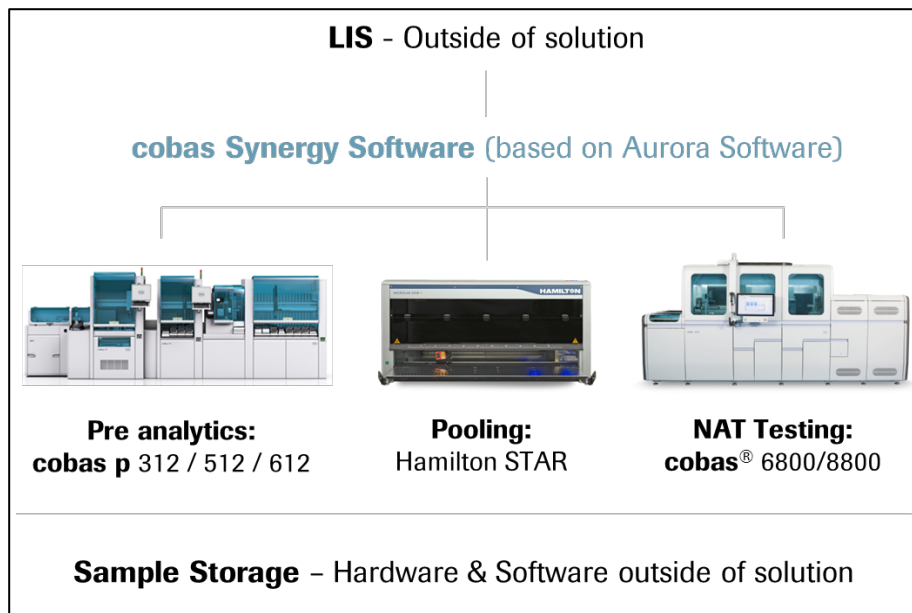
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Establishment number:	3003966680		
Date Prepared:	09 March 2017		
Device Trade/Proprietary Name:	cobas Synergy Software		
Device Common/Usual Name:	Blood Establishment Computer Software		
Regulation Number:	21 CFR 862.2570		
Regulation Name:	Instrumentation for Clinical Multiplex Test Systems		
Class:	II		
Product Code:	PQQ (Data Acquisition Software)		
Predicate Device:	BK130052: Procleix NAT Manager Software (Version 1.1)		

Device Description:

cobas Synergy Software, is software that supports a high-throughput blood analysis solution intended to be used by large blood banks and plasma fractionators that test between 3,000 and 60,000 samples per day. To achieve this level of throughput, the software integrates a network of sample pooling instruments (Hamilton STAR) and cobas® 6800/8800 Systems for NAT, and manages the overall blood analysis sample workflow. Optionally, pre-analytics systems can be integrated as well via a file in ASTM 1394-97 format (LIS2-A2), generated by DI middleware connected to several pre-analytics instruments in echo mode middleware.

Figure 1 presents a high-level overview of the “cobas Synergy Software” functional architecture and interfaces to pre-analytics, sample pooling, and NAT (cobas 6800/8800 Systems). Note in this figure, (b) (4) (the product name during initial development) represents cobas Synergy Software.

Figure 1: cobas Synergy Software – High-throughput Blood Analysis Solution



The software further supports lab operators by providing instructions to transfer samples between instruments, as well as sample storage and aliquot plate locations. It registers each incoming sample and tracks its location and status throughout the entire workflow. In addition, the software has the ability to be integrated into the customer’s laboratory IT environment by providing an ASTM host interface.

The software is designed to collect data from assays, instruments, and pooling software, which

allows operators to track individual donor samples (organ and tissue donors, including cadaveric samples) and link them to the appropriate test results. The software collates the test results of pooled and non-pooled samples, assigns outcomes to individual 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 to shape and optimise the flow of data through the system while still keeping within defined boundaries. User access is controlled via inbuilt user security system.

The software can receive and process sample and result data at two levels: Where instrumentation is capable of performing its own data reduction in the processing of 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 reduction.

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

Intended Use:

cobas Synergy Software is software which manages samples to be processed on pre-analytic instruments as a front-end to the cobas® 6800/8800 Systems. The solution collects data from pooling and analyser instruments which allows the operator to review results against individual samples and samples which have been pooled, creating output files from the data that can be sent to a Laboratory Information Management System.

cobas Synergy Software is intended for use by Blood Establishment personnel who are trained in its operation and are familiar with the associated assays and instruments.

Technological Characteristics:

The similarities and differences between the technological characteristics for the predicate device Procleix NAT Manager™ Software and the cobas Synergy Software are summarized in Table 1 and Table 2, respectively.

Table 1: Similarities between the cobas Synergy Software and Predicate Device

Characteristic	Procleix NAT Manager™ Software (Predicate Device)	cobas Synergy Software (Submitted Device)
Intended Use	<p>Procleix NAT Manager® Software is designed to collect data from Procleix® assays, instruments, and pooling software, which allows operators to track individual donor samples (organ and tissue donors, including cadaveric samples) and link them to the appropriate test results. The software collates the results of pooling and testing, assigns outcomes to individual samples according to a testing algorithm, and formats output files that can be sent to a Laboratory Information Management System (LIMS).</p> <p>In addition, Procleix NAT Manager Software can be configured to verify that master pool tubes have the required mass by collecting gravimetric data before and after pooling (this function is optional). Procleix NAT Manager Software also produces a variety of summary informational and analytical reports.</p> <p>Procleix NAT Manager Software is intended to be used by Blood Establishment and Clinical Diagnostic Laboratory personnel who are trained in its operation and familiar with the Procleix assays, instruments, and pooling software.</p> <p>Reflex testing, worklist population, and export of final results can all be controlled via menu options or locked down and automated via user defined rule sets.</p> <p>Procleix NAT Manager Software manages test results for the Procleix assays and systems.</p>	<p>cobas Synergy Software is software which manages samples to be processed on pre-analytic instruments as a front-end to the cobas® 6800/8800 Systems. The solution collects data from pooling and analyser instruments which allows the operator to review results against individual samples and samples which have been pooled, creating output files from the data that can be sent to a Laboratory Information Management System.</p> <p>cobas Synergy Software is intended for use by Blood Establishment personnel who are trained in its operation and are familiar with the associated assays and instruments.</p> <p>Note: cobas Synergy does not require the gravimetric functionality as identified on the predicate device.</p>
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

Characteristic	Procleix NAT Manager™ Software (Predicate Device)	cobas Synergy Software (Submitted Device)
Open database connectivity (ODBC)?	Yes	Yes
Supported NAT instrument	Grifols Panther	cobas® 6800/8800
Supported Pooling Instrument	Grifols Procleix Xpress (Tecan Genesis)	Hamilton STAR
Sample Result Database	Yes	Yes
Pooling Manager	Yes	Yes
Reporting	Yes	Yes
Search & View	Yes	Yes
Data Entry	Yes	Yes
User Login	Yes	Yes
Configuration – Assay	Yes	Yes
Worklist	Yes	Yes
Configuration – Devices	Yes	Yes
Manager – System Settings	Yes	Yes
Manager - Security Access	Yes	Yes
Manager – Database Management	Yes	Yes
Manager – Database Locking	Yes	Yes
View Log	Yes	Yes
Monitor	Yes	Yes
Configuration – Worklist	Yes	Yes
Validate Module	Yes	Yes

Characteristic	Procleix NAT Manager™ Software (Predicate Device)	cobas Synergy Software (Submitted Device)
Result Approval	Yes	Yes

Table 2: Differences between the cobas Synergy Software and Predicate Device

Characteristic	Procleix NAT Manager™ Software (Predicate Device)	cobas Synergy Software (Submitted Device)
Gravimetrics	Yes	No
Configuration – Report	Yes	No
Configuration – Utilities	Yes	No
Support for pre-analytcs?	No	Yes
User-defined and/or pool size defined Quantitative Titer Cut-off?	No	Yes

The full table of substantial equivalence can be found in Section 012.

Based on an assessment of relevant technological characteristics, cobas® Synergy Software is substantially equivalent to Procleix NAT Manager™ Software. The full table of substantial equivalence can be found in Section 12.

Clinical Performance Evaluation

Analysis of clinical performance data was not relied on to support the determination of substantial equivalence between the cobas Synergy Software and predicate device Procleix NAT Manager™ Software.

Roche have performed various studies using physical instruments in a complete application environment. Details of these studies have been included with this submission in document *013_Appendix 5 Equivalence and Evaluation Studies*

Non-Clinical Performance Evaluation

Analysis of non-clinical performance data was relied on to support the determination of substantial equivalence between the cobas Synergy Software and predicate device Procleix NAT Manager™ Software.

Summary of Verification and Validation Results

Requirements testing and System testing with cobas Synergy Software has been performed and documented. Defects are logged in the defect tracking system. The defects have been analysed and classified during the testing phases to assist with the management of testing. Impact assessments were performed during all phases of testing by relevant personnel. Each

assessment includes a description, analysis, category of failure and impact assessment; where it is available the resolution is also recorded.

The remaining open defects have been mitigated or assessed to have an acceptable level of risk. A copy of the Test Summary Matrix is included in Appendix 9 and the list of unresolved anomalies in Section 16.

SAFETY AND EFFECTIVENESS DATA

Cobas Synergy Software is developed using established procedures for software development that encompasses design through software testing. Testing has been performed utilising unit testing and system level testing. The results of testing demonstrate that cobas Synergy Software meets the requirements of the intended use.

Testing

System testing of cobas Synergy Software was performed in a User facility (Roche Diagnostics International Ltd). The conclusion from testing demonstrates that cobas Synergy Software meets its specifications and functions as expected within its intended use. A summary of the test records are contained in 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 the cobas Synergy Software is substantially equivalent to predicate Procleix NAT Manager™ Software.

In summary, the intended use, technological characteristics, and functionality of the cobas Synergy 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, cobas® Synergy Software is safe and effective for its intended use.