

510(k) – Summary

As Required by Sec 807.92(c)

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Establishment Number:	3003966680
Date Prepared:	17 MAR 2017
Device Trade/Proprietary Name:	Procleix® NAT Manager® v1.2 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:	75PQQ (Data Acquisition Software)
Predicate Devices:	

<u>Company Name</u>	STRATEC Biomedical UK Limited Centrum Point, Third Avenue, Centrum 100, Burton upon Trent Staffordshire, DE14 2WD Great Britain
Device Trade Name	Procleix NAT Manager® Software (Version 1.1)
510 (k) #	BK 130052
Date Cleared	17 April, 2014

Device Description

Procleix NAT Manager Software is a software application used in blood screening that utilizes an SQL database to store data. Utilizing the same core functionality as its predicate device version 1.1, NAT Manager Software v1.2 further expands Procleix assay compatibility. It supports large pools, dual analyte assays, assays that require cell lysis and supports the tracking of sample locations when the Procleix pooler is used to archive samples without pooling them. It also enables customers to use their own servers for the SQL database. And it allows users to configure the automatic approval of valid, non-reactive conclusions or valid, below-cutoff conclusions.

There are several major uses of this software:

- 1) It is used to combine data from Procleix poolers and Procleix assay instruments to perform deconvolution of conclusions from tests of pools to individual constituents,
- 2) In the event of an assay that requires cell lysis, it is used to assign lysate test conclusions to the associated donation IDs,
- 3) It is used to provide a run status for each assay run using a combination of instrument calibrators, instrument controls, and external controls.
- 4) It is used to notify users that samples with a reactive result require additional testing,
- 5) It is used to provide a mechanism for the user to review and approve test results and conclusions before they are exported to the Laboratory Information Management System (LIMS).
- 6) It is used to configure the data that is exported in a way that is easy for the LIMS to import.

Intended Use / Indications for Use:

Procleix NAT Manager Software is designed to collect data from Procleix assays, instruments, and pooling/lysis software, which allows operators to track individual donor blood samples and link them to the appropriate test results. The software collates the results of lysing, 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). Procleix NAT Manager Software also produces a variety of summary informational and analytical reports.

Procleix NAT Manager Software is intended to be used by Blood Establishment personnel who are trained in its operation and familiar with the Procleix assays, instruments, and pooling and lysing software.

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.

Procleix NAT Manager Software manages test results for the Procleix assays and systems.

Technological Characteristics of the Procleix NAT Manager v1.2 Compared to the Predicate Device

Procleix NAT Manager v1.2 is substantially equivalent to Procleix NAT Manager v1.1 with the exception of the removing gravimetric feature.

Procleix NAT Manager Software v1.2 – New Functionality:

Procleix NAT Manager v1.2 uses the current Procleix NAT Manager Software (version 1.1) (BK130052) to provide the working database, core functionality and secure access to the data. Core functionality has been improved by the addition of a Large pooling module, management of a duplex assay (Parvo/HAV) and management of a lysing step for hematologic assays. Moreover, Functionality for user configuration of reports, the Monitor module and the Gravimetric module have been removed in the improvement step as these are no longer required.

Similarities and Differences between Procleix NAT Manager v1.2 and the Predicate Device:

The two devices have “the same technological characteristics”, as Procleix NAT Manager Software v1.2 utilizes the same software architecture and is operated on the same core functionality of the predicate device (BK130052). This core provides essential base functions including database, secure login, audit trails, data recall and print functions. The changes in functionality are as following:

Removal from new version

- GRAVIMETRICS MODULE: Optional configurable item that is no longer required. The feature has been made obsolete by upgrades to the Pooling instruments that mean the Gravimetric process is no longer performed.

Addition to new version

- Large Pooling: Changes to modules to allow pools where all of the constituents are master pools.
- Two Analyte Assay- Change to modules to allow management of a duplex assay (Parvo/HAV)
- Lysing- Modules to allow management of a lysing step for hematologic assays.

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

Summary of Verification and Validation Results

Requirements test and Systems Integration testing which included the use of all Procleix Instruments and peripheral systems compatible with NAT Manager version 1.2 were performed and documented. Defects were logged in tracking systems, the defects were analysed and classified during testing phases to assist with the management of testing. Impact assessments were performed during all phases of testing by relevant personnel. Each assessment included a description, analysis, category of failure, impact assessment, and actual resolution.

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

Brief Description of Performance Data

Procleix NAT Manager is a middleware solution designed to be used with other Procleix instruments and software.

The software is designed to handle NAT test results from both single sample testing and from pooled sample testing where aliquots of multiple samples will be pipetted and tested together in a single 'pool tube'. In the case of pool testing the software will manage the process of resolving the collective pool result back to the individual samples that make up the pool. Pool testing can be single assay or multiplex assay based.

While the software operates on a Microsoft Windows based platform, it has been optimised for use on a touch screen monitor, although standard mouse and keyboard input can be used.

SAFETY AND EFFECTIVENESS DATA

The NAT Manager v1.2 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 NAT Manager v1.2 meets the requirements of the intended use.

Testing

System Integration testing of NAT Manager v1.2 was performed in a User facility (Grifols Diagnostic Solutions Inc.). The conclusion from testing demonstrates that NAT Manager v1.2 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 NAT Manager v1.2 Software is technologically similar to predicate Procleix NAT Manger version 1.1. 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 NAT Manager v1.2 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, NAT Manager v1.2 Software is safe and effective for its intended use.