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5.0 SPECIAL 510(K) SUMMARY

As Required by 21CFR 807.92 (c)

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Date Prepared: December 19, 2017

Name of the Device:

Trade Name:	Procleix Xpress® System (Software v3.0)
Common Name:	Blood Pooling and Pipetting Instrument and Software
Classification Name:	Blood Establishment Computer Software and Accessories
Regulation Number	21 CFR 864.9175
Device Class:	Class II
Classification Product Code:	MMH

Identification of the Legally Marketed Device (Predicate Device):

Trade Name:	Procleix Xpress® System
Original Applicant:	Grifols Diagnostic Solutions Inc. 4560 Horton Street Emeryville, CA 94608
510(k) Number:	BK140150
Device Class:	Class II
Classification Product Code:	MMH
Date of Clearance:	27 August 2014

Device Description

The Procleix Xpress® System is an automated pooling platform consisting of a pipetting instrument and software. It is designed to pool blood and plasma donor specimens in preparation for Nucleic Acid Test (NAT). Utilizing the same core functionality as its predicate device, the Procleix Xpress System (Software v1.0), Xpress Software v3.0 further expands its pooling capability to larger pool sizes. Large pools are created using the "Pools of pools" concept, where large pools of plasma or serum are created from previously prepared master pools. Master pools are created from individual samples into a single Master Pool Tube (MPT); multiple master pools (MPTs) are subsequently pooled into a single Large Pool Tube (LPT). This process allows for a larger number of individual samples to be prepared on the Procleix Xpress System, and then tested during a single run on an automated testing (NAT) analyzer. There are four types of Large Pool runs:

- Pools of 48 (Created by pooling 6 tubes of MPT's of 8)
- Pools of 96 (Created by pooling 6 tubes of MPT's of 16)
- Pools of 96 (Created by pooling 12 tubes of MPT's of 8)
- Pools of 256 (Created by pooling 16 tubes of previously prepared MPT's pools of 16)

In addition, the Procleix Xpress System can be used to archive specimens into a deep well archive plate, either alone or with pooling runs of 4, 8 or 16.

The associated accessories include:

- Sample Rack Adapter with Carrier Flag
- Sample Racks with barcode flags
- Carriers for micro well plates
- Carrier for disposable tip racks
- Disposable tips waste slide and bag holder
- Cover for disposable tips waste slide

The device provides a variety of features that simplify the pipetting tasks, including air-based pipetting with no liquid waste disposal. In addition, the device does not require weighing Master Pool Tubes (MPTs) for confirming pipetting accuracy. The tips used with this device are compatible with Procleix Panther and Procleix Tigris systems. The device has a touchscreen which provides visual and audible status alerts. Archiving and pooling configurations are modifiable. The device provides cybersecurity via a firewall.

Intended Use

The Procleix Xpress® System (Software and Instrument) is intended to be used to create pools of human plasma or serum for blood screening tests for viral nucleic acids. The Procleix Xpress® System automatically transfers plasma or serum from individual samples into a single master pool tube, which may be used for further testing in Procleix® systems. The Procleix Xpress® System also collects barcode data from all tubes, racks, and archive plates used in a given pooling run, establishing positive specimen identification and Master Pool Tube (MPT) composition. In addition, the Procleix Xpress® System can be used to dispense human plasma or serum aliquots into an archive plate.

Technological Characteristics of the Procleix Xpress® System (Software v3.0) Compared to the Predicate Device

Procleix Xpress System Software v3.0 is substantially equivalent to its predicate device as summarized in the tables below:

Similarities

Feature/ Functionality	Predicate Device (BK140150) Procleix Xpress® System (Software v1.0)	Proposed Device Procleix Xpress® System (Software v3.0)
Intended Use	Pooling Pipettor	Same
Indications for Use	The Procleix Xpress® System (Software and Instrument) is intended to be used to create pools of human plasma or serum for *in-vitro* diagnostic testing, such as blood screening tests for viral nucleic acids. The Procleix Xpress® System automatically transfers plasma or serum from individual samples into a single master pool tube, which may be used for further testing in Procleix® systems. The Procleix Xpress® System also collects barcode data from all tubes, racks, and archive plates used in a given pooling run, establishing positive specimen identification and Master Pool Tube (MPT) composition. In addition, the Procleix Xpress® System can be used to dispense human plasma or serum aliquots into an archive plate. Note: Procleix systems" refers to any equipment platform in the Procleix product line. Regulatory approvals and commercial availability vary by region.	The Procleix Xpress® System (Software and Instrument) is intended to be used to create pools of human plasma or serum for blood screening tests for viral nucleic acids. The Procleix Xpress® System automatically transfers plasma or serum from individual samples into a single master pool tube, which may be used for further testing in Procleix® systems. The Procleix Xpress® System also collects barcode data from all tubes, racks, and archive plates used in a given pooling run, establishing positive specimen identification and Master Pool Tube (MPT) composition. In addition, the Procleix Xpress® System can be used to dispense human plasma or serum aliquots into an archive plate.
Liquid pipetting platform	Yes	Same
Liquid level detection	Yes	Same
Barcode sample tracking	Yes	Same
Safety shield panels	Yes	Same
External computer	Yes	Same
Pools individual samples into one tube	Yes	Same

Feature/ Functionality	**Predicate Device (BK140150) Procleix Xpress® System (Software v1.0)**	**Proposed Device Procleix Xpress® System (Software v3.0)**
Pooling Software	Yes, version 1.0	Yes, version 3.0
Multi pipetting	Yes, 8 Channels	Same
Clot detection	Yes	Same
Uses Disposable tips	Yes	Same
Hand held scanner	Yes	Same
Archiving of Samples	Yes	Same
Pooling Data Output	Yes, Pool File	Same
Access control	UserID/password credentials. Two users levels: User and Supervisor	Same
Target Population	Donated blood samples	Same
LAN Connectivity	Yes	Same
Error Message Concept	Yes	Same
File Archiving	Yes	Same
Pooling Sizes : P4, P8, P16	Yes	Same
Firewall	Yes	Same

Differences

Features/ Functionality	**Predicate Device (BK140150) Procleix Xpress® System (Software v1.0)**	**Proposed Device Procleix Xpress® System (Software v3.0)**
Pooling Sizes: P48, P96, P256	No	Yes
Accessories: Use of Panther Rack Adapter	No	Yes

Main features introduced with software version 3.0

The following new features have been implemented in the Xpress Software v3.0:

- Creation of Large Pools
  - Creation of pools of 48 (6 x MPT of 8)
  - Creation of pools of 96 (12 x MPT of 8)
  - Creation of pools of 96 (6 x MPT of 16)
  - Creation of pools of 256 (16 x MPT of 16)
- Use of Panther Rack Adapters to allow pooling into the Procleix Panther sample rack

A detailed Revision History from software version 1.0 to 3.0 is described in **Section 009 Description of Modified Device** of this submission**.**

Summary of Design Control Activities

Product Risk Management: Hazard analysis was performed at both system and software levels to assess the impact of the modification on the device. Total of 13 risks specific to Procleix Xpress System Software v3.0 were identified, of which three were assessed as "unacceptable" before risk control. These three risks were successfully mitigated by design and were reassessed for risk acceptability. There were NO "unacceptable" residual risks after mitigations and verification of all mitigations was completed.

Cybersecurity Risk Management: Analysis of cybersecurity vulnerabilities was conducted in accordance with FDA's pre-market and post-market cybersecurity management guidance. There were no potential cybersecurity events identified which were associated with an unacceptable risk of harm to a donor, operator, or blood product recipient. Each of the risk mitigations was verified with acceptable results. Furthermore, requirements regarding cybersecurity controls are provided in the Operator's Manual.

Design Verification and Validation: V&V were conducted in accordance with the product V&V plan, including software installation, Unique Device Identifier (UDI) display, and creation of large pools (48, 96, and 256), system integration and compatibility with Procleix Panther System. As demonstrated by the V&V reports included with this submission, Procleix Xpress System Software v3.0 and its specifications (design outputs) meet the product requirements (design inputs), and conform to the user needs and intended use; as such, the device modifications DO NOT raise different questions of safety and effectiveness and the device is as safe and effective as the legally marketed device (as defined in section 513(i)(1)(B) of the FD&C Act).

The Declaration of Conformity: Declaration of Conformity with Design Controls and Declaration of Conformity with 21 CFR 820.20 is provided in this submission.

Conclusion

Grifols Diagnostic Solutions has demonstrated through its evaluation and testing that the Procleix Xpress System Software v3.0 is substantially equivalent to the legally marketed Procleix Xpress System (Software v1.0). A hazard analysis and cybersecurity risk analysis have been performed and all hazards have been mitigated. Each of the risk mitigations was verified with acceptable results. Like its predicate device, the Procleix Xpress System Software v3.0 is safe and effective for its intended use.