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Device Trade/Proprietary Name: Pool Results Manager Version 1.0C including Module for Roche NAT Testing Version 2.0A

Device Common/Usual Name: Blood Establishment Computer Software

Classification: Product Code MMH

Predicate Device: Rubin & Poor Procleix® NAT Tracker 2.0 ("NAT Tracker")
510(k) number: BK030030

Date Prepared: August 26, 2008

Device Description and Intended Use:

Pool Results Manager (PRM) is intended to be used by personnel trained in its operation. The software combines data from testing and pooling sources to assign testing outcomes to blood unit IDs. Information from PRM is used to eliminate plasma units from the plasma production process.

PRM receives pooling data that defines the constituent units of pools, and collates this data with imported test result data to arrive at testing conclusions for individual unit IDs. These conclusions are then available for lookup and reporting within PRM, as well as export via creation of output files in various formats.

Specifically, PRM provides the following functionality:

- Import of pool files
- Import of test results
- Collation of test results to individual pool constituents
- Interpretation of these test results to determine testing conclusions
- Lookup of units and pools for query, revision, reporting
- Printing of exception reports and production reports
- Export of testing conclusions
- Flexible security capabilities to restrict access to critical functions to authorized users.

PRM has been configured for the following tests:

- Parvo B19
- Roche NAT assays for HIV-1, HCV and HBV

Technological Characteristics:

NAT Tracker collates electronic data generated by a pooling device and a testing source to associate test results with the corresponding sample IDs. PRM collates electronic data files generated by a pooling device and testing data to associate test results with the corresponding IDs. Both software applications pooled sample data and associate the results with individual unit IDs.

Both software applications utilize databases to store the data received from the different sources, as well as the resulting collated data and associated testing outcomes. Both applications create an electronic file of the testing outcomes for retrieval by a laboratory information system.

Both NAT Tracker and PRM use case logic rules to assign testing outcomes. The PRM case logic rules have been fully validated to ensure that the application assigns testing outcomes in accordance with the system specifications.

Conclusion:

Based on specific information provided in the 510(k) notification for Pool Results Manager Version 1.0C regarding software requirements, design, development, verification and validation, hazard analysis assessment and performance testing results, the software has been demonstrated to be safe and effective for its intended use.