ABBREVIATED 510(K) SUMMARY

SUBMITTER: Ortho-Clinical Diagnostics, Inc.
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DEVICE NAME/CLASSIFICATION NAME:

Trade name: Ortho®Lab with Ortho®Lab IC
Classification name: Blood Establishment Computer Software

SUBSTANTIAL EQUIVALENCE CLAIMED TO:

1. BloodCare - LifeTrak Lab Version 2.01 – 510(k) Number: BK940048

2. Wyndgate Technologies - Safe Trace Version 1.0- 510(k) Number: BK950059

DEVICE DESCRIPTION:

Ortho®Lab is software designed to manage data associated with samples from blood units and other appropriate samples and tests (e.g., licensed in-vitro diagnostic assays, blood typing) performed on those samples. It allows automated and/or manual test data generated from different types of laboratory instruments to be tracked in one place. Once test data is collected by the Ortho®Lab application, a user can review, disposition, store, and print and, if desired, transfer appropriate data to another remotely located Ortho®Lab Application. Ortho®Lab supports Testing Center operations whether receiving samples to test from multiple numbers of Collection Centers, serving internal testing needs, or external customer testing needs. The Ortho®Lab IC (Instrument Concentrator) is accessory software that receives information/data from laboratory instruments and systems and transfers this information/data in a generic formatted file to the Ortho®Lab application database.

INTENDED USE:

Ortho®Lab is data management software intended to assemble and correlate automated and/or manual test data information by unique identification number for samples from blood units collected by a Collection Center or for other samples tested with licensed in-vitro diagnostic assays and reagents at a Testing Center. Data can include unit collection information, sample identification registration, test instrument registration and qualification, reagent component registration and qualification, and laboratory workstation information.

Ortho®Lab IC (Instrument Concentrator) is an accessory to the Ortho®Lab application that is responsible for accepting test results from automated instruments and transferring these results to the Ortho®Lab application or any other application capable of accepting test results in the Ortho®Lab IC generated generic formatted file.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS:

Ortho®Lab is data management software that is able to track testing data generated at a Testing Center. Test result and assay processing parameters can be manually entered into the Ortho®Lab application. Test results can be uploaded from automated laboratory instruments via the Ortho®Lab IC. In addition, Ortho®Lab supports test order generation by a Collection Center and the electronic transmission of such data to a Testing Center. Ortho®Lab also supports test result generation and the electronic transmission of such data to a Collection Center or other appropriate facility.