Ortho Clinical Diagnostics

FDA 510(k) Clears ORTHO CONNECT™ Middleware Solution from Ortho Clinical Diagnostics

March 26, 2018

Offering "one connection, complete control" through simplified data management, ORTHO CONNECT V2.0 is now commercially available in the United States

Ortho Clinical Diagnostics (Ortho), a global leader of in vitro diagnostics, today announced that its ORTHO CONNECT V2.0 middleware solution received 510(k) clearance by the U.S. Food and Drug Administration (FDA). ORTHO CONNECT is a comprehensive, integrated and customizable middleware system that centralizes laboratory operations and workflow across hospitals and networks, allowing blood banks and their data to be confidently managed through one central terminal. It also enables the ORTHO VISION® and ORTHO VISION® Max immunohematology analyzers, which test blood for transfusion compatibility, to integrate with a hospital's Laboratory Information Systems (LIS) through a single validated connection to exchange data and simplify processes. ORTHO CONNECT V2.0 is now available for purchase in the United States.

"Ortho is focused on diminishing the complexities of immunohematology testing while improving safety, speed and efficiency throughout the blood bank," said Robert Yates, Ortho's chief operating officer. "ORTHO CONNECT does just that, bringing improved functionality to Laboratory Information Systems that are often relatively rigid and outdated. It's the perfect complement to our ORTHO VISION platform of analyzers."

ORTHO CONNECT provides labs with highly customizable middleware that allows them to consolidate operations and workflow across lab networks. Acting as an intermediary between instruments and Lab Information Systems, it allows labs to exchange data, perform data management, and complete regulatory process tasks that are not easily performed alone. ORTHO CONNECT allows labs to centralize lab operations and workflow across their network so all test results on connected analyzers can be viewed, verified and interacted with no matter the location, as well as simplify data management and the testing process through lab network connectivity. Through this functionality, ORTHO CONNECT works to support a lab's ability to improve safety and efficiency at every step of the testing process. By bridging the gap between instruments and hospital sites, ORTHO CONNECT centralizes data access and management for greater control.

ORTHO CONNECT strengthens Ortho's transfusion medicine portfolio capabilities. It was developed to address the myriad demands placed on lab managers, whose limited staff have diverse skill sets and are asked to serve an expanding array of health networks. With cost containment and increased haemovigilance top of mind, lab managers need to consolidate and standardize their instruments while optimizing both automation and workflow. On top of resource challenges, there is increasing testing volume and data complexity due to a population that is living longer and with more complicated conditions. ORTHO CONNECT efficiently manages this high variability to keep large quantities of data accessible and consistent across multiple instruments and laboratory systems and works seamlessly with the comprehensive, integrated and scalable suite of products Ortho developed for Immunohematology labs.

About Ortho Clinical Diagnostics

Ortho Clinical Diagnostics is a global leader of in vitro diagnostics serving the clinical laboratory and immunohematology communities. Across hospitals, hospital networks, blood banks and labs in more than 125 countries and territories, Ortho's high-quality products and services enable health care professionals to make better-informed treatment decisions. For the immunohematology community, Ortho's blood typing products help ensure every patient receives blood that is safe, the right type and the right unit. Ortho brings sophisticated testing technologies, automation, information management and interpretation tools to clinical laboratories around the world to help them run more efficiently and effectively and improve patient care. Ortho's purpose is to improve and save lives with diagnostics, and it does that by reimagining what's possible. This is what has defined Ortho for more than 75 years, and it's what drives Ortho forward.

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