Our STN: BL 103778/5106

SUPPLEMENT APPROVAL
February 10, 2026

Ortho-Clinical Diagnostics, Inc.
Attention: Darlene J. Phillips
100 Indigo Creek Drive
Rochester, NY 14626

Dear Darlene Phillips:

We have approved your request received October 17, 2025, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for Reagents Red Blood Cells to add labeling for the continuous on-board storage of the ORTHO 0.8% RESOLVE® Panels, A, B, and C on the automated ORTHO VISION® and ORTHO VISION® Max analyzers.

LABELING

We hereby approve the draft package insert labeling submitted under amendment # 5000, dated December 10, 2025. This is a reminder that as of September 24, 2014, medical devices that are licensed under the PHS Act are subject to certain provisions of the final Unique Device Identifier (UDI) rule. These provisions include the requirement to provide a UDI on the device label and packages (21 CFR 801.20), format dates on the device label in accordance with 21 CFR 801.18, and submit data to the Global Unique Device Identification Database (GUDID) (21 CFR 830 Subpart E). Additionally, please identify each device identifier implemented for the subject device, and the device identifiers that have been discontinued for the subject device as a labeling change in an annual report consistent with 21 CFR 601.12(f)(3). For more information on these requirements, please see the UDI website at http://www.fda.gov/udi.

Please submit all final printed labeling as PDF electronic copy (eCopy) at the time of use and include implementation information on Form FDA 356h as appropriate.

Two draft copies of the proposed introductory advertising or promotional labeling may be voluntarily submitted for advisory comment with a completed Form FDA 2253 to the Advertising and Promotional Labeling Branch at the following address:

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Ave.
WO71–G112
Silver Spring, MD 20993-0002

For each pending supplemental application for this BLA that includes proposed revised labeling, please submit an amendment to update the proposed revised labeling with the changes approved today.

We will include information contained in the above-referenced supplement in your BLA file.

Sincerely,

Wendy Paul, MD
Director
Division of Blood Components and Devices
Office of Blood Research and Review
Center for Biologics Evaluation and Research