DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

Ortho-Clinical Diagnostic, Inc.
Attention: Mr. Kevin Wyckoff
1001 U.S. Highway 202,
Raritan, NJ 08869

510(k) SE LETTER

Re:	BK140207
Trade/Device Name:	ORTHO VISION™ Analyzer
Regulatory Number:	21 CFR 864.9175
Regulatory Name:	Automated Blood Grouping and Antibody Test System
Regulatory Class:	Class II
Product Code	KSZ
Dated:	July 16, 2015
Received:	July 17, 2015

Dear Mr. Wyckoff:

We have reviewed your Section 510(k) premarket notification of intent to market the devices referenced above and have determined the devices are substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28,1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the devices, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your devices in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your devices complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809**]**);; medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the

electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, ″Misbranding by reference to premarket notification″ (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Richard J. Davey, MD
Director
Division of Blood Components and Devices
Office of Blood Research and Review
Center for Biologics
Evaluation and Research

Enclosure
Indication for Use

Indications for Use

510(k) Number: BK140207

Device Name: ORTHO VISION™ Analyzer

Indications For Use:

ORTHO VISION™ Analyzer is an instrument designed to automate in vitro immunohematology testing of human blood utilizing the ID-MTS™ gel card technology. ORTHO VISION™ Analyzer automates test processing functions including liquid pipetting, reagent handling, incubation, centrifugation, reaction grading and interpretation and data management requirements using cards and digital image processing. ORTHO VISION™ Analyzer can be used as a standalone instrument or interfaced to the customer's Laboratory Information System (LIS).

Prescription Use__X__ AND/OR Over-The-Counter Use__
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CBER, Office of Blood Research and Review

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Division Sign-Off
Office of Blood Research and Review