2.0 510(k) SUMMARY INFORMATION

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

1.1 Name, Address of Applicant and Contact Person

Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, New York 14626-5101
(585) 453-3730

Contact Person: Charlotte Baker

DEC 26 2006

1.2 Preparation Date

October 13, 2006

1.3 Device Trade or Proprietary Name

VITROS Immunodiagnostic Products Rubella IgG Reagent Pack
VITROS Immunodiagnostic Products Rubella IgG Calibrators

Common Name: Rubella IgG Assay

1.4 Classification (Generic) Name of Device

Immunoassay Method, Rubella IgG Method
Regulation 866.3510
Class: 2
Product Code: LFX

1.5 Predicate Device

ABBOTT AxSYM Rubella IgG Assay: K954045.

1.6 Device Description

The VITROS Rubella IgG assay is performed using the VITROS Immunodiagnostic Products Rubella IgG Reagent Pack and VITROS Immunodiagnostic Products Rubella IgG Calibrators on the VITROS Immunodiagnostic System for the qualitative and quantitative determination of rubella IgG antibodies to rubella virus in human serum and plasma. An immunometric technique is used. This involves the reaction of anti-rubella IgG present in the sample with rubella antigen coated onto the wells. After a wash step a horseradish peroxidase (HRP)-labeled antibody conjugate (mouse monoclonal anti-human IgG) is added and this complexes with bound anti-rubella IgG. Unbound materials are removed by washing.

The bound HRP conjugate is measured by a luminescent reaction. A reagent containing luminogenic substrates (a luminol derivative and a peracid salt) and an electron transfer agent, is added to the wells. The HRP in the bound conjugate catalyzes the oxidation of the luminol derivative, producing light. The electron transfer agent (a substituted acetanilide) increases the level of light produced and prolongs its emission. The light signals are read by the VITROS Immunodiagnostic System. The amount of HRP conjugate bound is directly proportional to the concentration of anti-rubella IgG present.

1.7 Device Intended Use

For *in vitro* diagnostic use only.

The VITROS Immunodiagnostic Products Rubella IgG assay is intended for the quantitative determination of IgG antibodies to rubella virus in human serum and plasma (heparin, EDTA or sodium citrate) using the VITROS Immunodiagnostic System.

The VITROS Rubella IgG assay is for use in the clinical laboratory to aid in the determination of immunity to rubella virus infection.

1.8 Comparison to Predicate Device

The VITROS Rubella IgG Reagent Pack and Calibrators are substantially equivalent to the ABBOTT AxSYM Rubella IgG Assay (predicate device) which was cleared by the FDA (K954045) for IVD use.

Table 1 (next page) presents the similarities and differences of both assays.

Table 1 Assay Characteristics

Similarities		
Device Characteristic	**New Device-VITROS Rubella IgG assay**	**Predicate Device-ABBOTT AxSYM Rubella IgG assay**
Intended Use	For *in vitro* diagnostic use only. The VITROS Immunodiagnostic Products Rubella IgG assay is intended for the quantitative determination of IgG antibodies to rubella virus in human serum and plasma (heparin, EDTA or sodium citrate) using the VITROS Immunodiagnostic System. The VITROS Rubella IgG assay is for use in the clinical laboratory as an aid in the determination of immunity to rubella virus infection.	The AxSym Rubella IgG assay is a Microparticle Enzyme Immunoassay (MIA) for the qualitative and quantitative measurement of IgG antibodies to rubella virus in serum or plasma (EDTA, heparin or sodium citrate) to aid in the determination of immune status to rubella.
Basic principle	Solid phase immunoassay	Solid phase immunoassay
Tracer	Enzyme labeled	Enzyme labeled
Instrumentation	Automated Immunoassay System	Automated Immunoassay System
Sample type	Serum and plasma (EDTA, heparin, or sodium citrate)	Serum and plasma (EDTA, heparin, or sodium citrate)
Antigen virus strain	HPV-77	HPV-77
Calibrator format	Liquid	Liquid
Linearity with W.H.O. 1st International standard-Assay range	r = 0.999	r = 0.9999
Linearity with W.H.O. 1st International standard from 0-20 IU/mL	r = 0.9988	Unknown
CDC Panel evaluation	Yes	Yes
Positive % Agreement/ Initial Sensitivity	Study 1: 98.6% Study 2: 97.5%	99.5%
Negative % Agreement/ Initial Specificity	Study 1: 91.1% Study 2: 98.3%	90.8%
Calibrators referenced to W.H.O.	Yes	Yes
CLSI Standards Used	I/LA6, EP5, EP6, EP7, EP9	I/LA6, EP5
Differences		
Antibody	Mouse monoclonal anti-human IgG	Goat anti-Human IgG
Sample volume	10µL	180µL
Calibrator levels	3	6
Reportable range	0-350 IU/mL	0-500 IU/mL
Incubation time and temperature	35 minutes at 37°C	20 minutes at 37°C

1.9 Conclusions

The data presented in the premarket notification provide a reasonable assurance that the VITROS Rubella IgG Assay is safe and effective for the stated intended use and is substantially equivalent to the cleared predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ortho-Clinical Diagnostics, Inc.
c/o Charlotte Baker
100 Indigo Creek Dr.
Rochester, NY 14626

DEC 26 2006

Re: k063143
Trade/Device Name: VITROS Immunodiagnostic Products Rubella IgG Reagent Pack
VITROS Immunodiagnostic Products Rubella IgG Calibrators
Regulation Number: 21 CFR 866.3510
Regulation Name: Rubella virus serological reagents
Regulatory Class: Class II
Product Code: LFX
Dated: December 13, 2006
Received: December 14, 2006

Dear Ms. Baker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is 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 device, 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 such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device 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 device 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 Part 801); 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. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0443. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sally A. Hojvat
Director, Division of Microbiology Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

1.0 STATEMENT OF INTENDED USE

510(k) Number (if known): K063143

Device Name: VITROS Rubella IgG Reagent Pack
VITROS Rubella IgG Calibrators

Indications for Use: VITROS Rubella IgG Assay

For in vitro diagnostic use only.

The VITROS Immunodiagnostic Products Rubella IgG assay is intended for the quantitative determination of IgG antibodies to rubella virus in human serum and plasma (heparin, EDTA or sodium citrate) using the VITROS Immunodiagnostic System.

The VITROS Rubella IgG assay is for use in the clinical laboratory to aid in the determination of immunity to rubella virus infection.

Prescription Use ✓ 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)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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