SEP 2 0 2004

Chapter 1 – Summary Information

510(k) Summary

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.

The assigned 510(k) number is: K041863

1. **Submitter name, address, contact**

Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, New York 14626-5101
(585) 453-4041

Contact Person: Marlene A. Hanna

2. **Preparation date**

Date 510(k) prepared: July 8, 2004

3. **Device name**

Trade or Proprietary Name:
VITROS Chemistry Products RF Reagent
VITROS Chemistry Products Calibrator Kit 16
VITROS Chemistry Products FS Calibrator 1
VITROS Chemistry Products RF Performance Verifiers I and II

Common Name: RF assay

Classification Name: Rheumatoid factor immunological test system (866.5775):
Class: II (performance standards)

Classification Name: Quality Control material (assayed and unassayed) (862.1660):
Class I (general controls). Since this device is an assayed control, it meets the reserved criteria under Section 510(l) of the Food, Drug, and Cosmetic Act.

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4. Predicate Device

a. The VITROS Chemistry Products RF assay is substantially equivalent to the Cobas Integra Reagent Cassette for Rheumatoid Factors II (RF-II) assay.

b. The VITROS Chemistry Products RF Performance Verifiers I and II are substantially equivalent to the VITROS Chemistry Products Performance Verifiers I and II.

5. Device description

The VITROS 5,1 FS Chemistry System is a fully automated clinical chemistry analyzer intended for use in the *in vitro* determination of various analytes in human specimens (serum, plasma, urine, and cerebrospinal fluid). The VITROS 5,1 FS is designed for use with VITROS Chemistry Products MicroTip and Thin Film assays.

The system is comprised of four main elements:

1. The VITROS 5,1 FS Chemistry System – instrumentation, which provides automated use of the chemistry reagents. The VITROS 5,1 FS Chemistry System was cleared for market by a separate 510(k) premarket notification (K031924).

2. The VITROS Chemistry Products MicroTip range of liquid reagent products (in this case VITROS Chemistry Products RF Reagent, VITROS Chemistry Products Calibrator Kit 16 and VITROS Chemistry Products FS Calibrator 1, VITROS Chemistry Products RF Performance Verifiers I and II), which are combined by the VITROS 5,1 FS Chemistry System to perform the VITROS RF assay.

3. The VITROS Chemistry Products Thin Film range of dry products, which are dry, multilayered, analytical elements, coated on polyester supports. The thin film products each have their own 510(k) clearance numbers and were cleared for market for use on the VITROS 5,1 FS Chemistry System through submission of information required by the ODE Guidance Document: "Data For Commercialization Of Original Equipment Manufacturer, Secondary and Generic Reagents For Automated Analyzers". The required information was provided in the VITROS 5,1 FS Chemistry System premarket notification (K031924).

4. Common reagents used by multiple assays on the VITROS System (in this case, VITROS Chemistry Products FS Diluent Pack 2 and VITROS Chemistry Products FS Reconstitution Diluent).

The VITROS System and reagents are designed specifically for use with the VITROS Chemistry Products range of products.

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6. Device intended use

a. VITROS Chemistry Products RF Reagent: For *in vitro* diagnostic use only. VITROS Chemistry Products RF Reagent is used to quantitatively measure rheumatoid factor (RF) concentration in human serum and plasma.

b. VITROS Chemistry Products Calibrator Kit 16 and VITROS Chemistry Products FS Calibrator 1: For *in vitro* diagnostic use only. VITROS Chemistry Products Calibrator Kit 16 is used in conjunction with VITROS FS Calibrator 1 to calibrate VITROS 5,1 FS Chemistry Systems for the quantitative measurement of rheumatoid factor (RF).

c. **VITROS Chemistry Products RF Performance Verifiers I and II:** For *in vitro* diagnostic use only. VITROS Chemistry Products RF Performance Verifiers I and II are assayed controls used to monitor the performance of RF Reagent on VITROS 5,1 FS Chemistry Systems.

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7. Comparison to predicate device(s):

Reagent Pack and Calibrators

The VITROS Chemistry Products RF Reagent and VITROS Chemistry Products Calibrator Kit 16 and FS Calibrator 1 are substantially equivalent to the Cobas Integra Reagent Cassette for Rheumatoid Factors II (RF-II) assay (predicate device) which was cleared by the FDA (K000534) for IVD use.

The relationship between the VITROS RF and the predicate device, determined by least squares linear regression, is:

$$\text{VITROS RF} = 0.904 \times X - 4.045 \text{ (IU/mL)},$$

with a correlation coefficient of 0.986,
where X is the Cobas Integra Reagent Cassette for Rheumatoid Factors II (RF-II) assay.

In addition to the above mentioned correlation study, studies were performed to determine the precision, specificity, linearity, antigen excess, lower limit of detection, and expected values of the VITROS RF assay, (refer to the VITROS RF Reagent Instructions for Use for summaries of the results of these studies).

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Table 1 lists the characteristics of the assays performed using the VITROS RF assay and the Cobas Integra Reagent Cassette for Rheumatoid Factors II (RF-II) assay.

Table 1

Table 1 lists the characteristics of the VITROS RF (new device) and the RF (predicate device).

Device Characteristic	**VITROS RF (New device)**	**RF (Predicate device)**
Intended Use	For *in vitro* diagnostic use only. VITROS Chemistry Products RF Reagent is used to quantitatively measure rheumatoid factor (RF) concentration in human serum and plasma.	The cassette COBAS INTEGRA Rheumatoid Factors II (RF-II) contains an *in vitro* diagnostic reagent system intended for use on COBAS INTEGRA systems for the quantitative immunological determination of human rheumatoid factors in serum and plasma.
Method	Immunoturbidimetric	Immunoturbidimetric
Reportable Range	6- 120 IU/mL	0-120 IU/mL
Sample Type	Serum and Plasma (heparin and EDTA)	Serum and Plasma (heparin, EDTA, Citrate)
Reactive Ingredient	Latex particles coated with human IgG	Latex particles coated with human IgG
Instrumentation	VITROS 5,1 FS Chemistry System	COBAS INTEGRA Systems
Wavelength	575 nm	583 nm

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Performance Verifiers

The VITROS Chemistry Products RF Performance Verifiers I and II are substantially equivalent to the VITROS Chemistry Products Performance Verifiers (predicate device) which were cleared by the FDA (K904768) for IVD use.

Table 2 lists the similarities and differences of the device characteristics between the VITROS RF Performance Verifiers I and II with the predicate device, the VITROS Performance Verifiers I and II.

Table 2

Device Characteristic	VITROS RF (New Device)	RF (Predicate Device)
Intended Use	For *in vitro* diagnostic use only. VITROS Chemistry Products RF Performance Verifiers I and II are assayed controls used to monitor the performance of RF Reagent on VITROS 5,1 FS Chemistry Systems.	For *in vitro* diagnostic use only. VITROS Chemistry Products Performance Verifiers I and II are assayed controls used to monitor the performance of VITROS Chemistry Systems.
Matrix	A base matrix of freeze-dried human serum to which purified human proteins, bovine serum albumin and preservative have been added.	A base matrix of freeze-dried human serum to which enzymes, electrolytes, stabilizers, preservatives and other organic analytes have been added.
Performance Verifier Levels	Low and High	Low and High

Conclusions

The data presented in the premarket notification provide a reasonable assurance that the VITROS RF assay and the VITROS Chemistry Products RF Performance Verifiers are safe and effective for the stated intended uses and are substantially equivalent to the cleared predicate devices.

Equivalence to predicate(s) was demonstrated using commercially available reagents along with patient samples.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
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SEP 2 0 2004

Re: k041863
Trade/Device Name: VITROS Chemistry Products RF Reagent,
VITROS Chemistry Products Calibrator Kit 16,
VITROS Chemistry Products FS Calibrator 1,
VITROS Chemistry Products RF Performance Verifiers I and II,
Regulation Number: 21 CFR § 866.5775
Regulation Name: Rheumatoid Factor Immunological Test System
Regulatory Class: II
Product Code: DHR, JIT, JJX
Dated: July 8, 2004
Received: July 9, 2004

Dear Ms. Hanna:

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 Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Robert L. Becker, Jr., M.D., Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041863

Device Name(s):

VITROS Chemistry Products RF Reagent
VITROS Chemistry Products Calibrator Kit 16
VITROS Chemistry Products FS Calibrator 1
VITROS Chemistry Products RF Performance Verifiers I and II

Indications for Use:

For *in vitro* diagnostic use only. VITROS Chemistry Products RF Reagent is used to quantitatively measure rheumatoid factor (RF) concentration in human serum and plasma. Measurement of rheumatoid factor may aid in the diagnosis of rheumatoid arthritis.

For *in vitro* diagnostic use only. VITROS Chemistry Products Calibrator Kit 16 is used in conjunction with VITROS FS Calibrator 1 to calibrate VITROS 5,1 FS Chemistry Systems for the quantitative measurement of rheumatoid factor (RF).

For *in vitro* diagnostic use only. VITROS Chemistry Products RF Performance Verifiers I and II are assayed controls used to monitor the performance of RF Reagent on VITROS 5,1 FS Chemistry Systems.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Maria Chan

Division Sign-Off

Office of In Vitro Diagnostic **Device** Evaluation and Safety

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