AUG - 7 2003

Section I Summary Information

1 510(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: K031924

1.1 Submitter's Information

Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, New York 14626-5101
Phone: (585) 453-3768
Fax: (585) 453-3368

Contact Person:
Neil Greenberg, PhD
Manager, Regulatory Affairs

1.2 Date of Preparation: June 20, 2003

1.3 Device Proprietary Name(s)

VITROS 5,1 FS Chemistry System
VITROS Chemistry Products dHDL Reagent Pack
VITROS Chemistry Products Calibrator Kit 19
VITROS Chemistry Products FS Calibrator 1

Common Names:

Clinical chemistry analyzer
HDL Cholesterol assay

1.4 Classification Names

Discrete photometric chemistry analyzer for clinical use: 21 CFR 862.2160
Lipoprotein test system: 21 CFR 862.1475
Calibrator: 21 CFR 862.1150

1.5 Predicate Device(s)

New devices	Predicate devices
1. VITROS Chemistry Products 5,1 FS Chemistry System	1. VITROS 950 Chemistry System FDA 510(k) Number K946090 2. Bayer ADVIA 1650 Chemistry System FDA 510(k) Number K990346
2. VITROS Chemistry Products dHDL assay	3. Bayer Direct HDL Cholesterol II FDA Docket Number K982341

1.6 Intended Use Statement(s)

The VITROS 5,1 FS Chemistry System is a random access, fully automated clinical chemistry analyzer, intended for use in the in vitro quantitative measurement of a variety of analytes of clinical interest in certain biological fluids (depending on the analyte) such as serum, plasma, urine and cerebrospinal fluid.

The VITROS Chemistry Products dHDL assay is intended for the *in vitro* quantitative measurement of HDL cholesterol in human serum or plasma.

1.7 Device Description

1.7.1 The VITROS 5,1 FS Chemistry System is a fully automated, computer controlled, clinical chemistry analyzer intended for the in vitro determination of a variety of general chemistries, therapeutic drugs, drugs of abuse, proteins and other chemistries of clinical interest in biological fluids such as serum, plasma, urine and cerebral spinal fluid (sample type is chemistry dependent). The system has been designed for high volume clinical in-vitro diagnostics applications. The analyzer operates in conjunction with reagents, calibrators and controls designed for use with the system. The instrument provides automatic dilution capability for all assays on board the system. The system analyzes up to 845 tests per hour with up to 40 analytes per sample. Major hardware components include a command center/operator interface, a sampling center, a disposable tip processing center, the VITROS Chemistry Slide General Chemistry center, and the VITROS MicroTip Special Chemistry processing center.

1.7.2 The VITROS Chemistry MicroTip range of products (in this case VITROS Chemistry Products dHDL Reagent Pack, VITROS Chemistry Products Calibrator Kit 19 and VITROS Chemistry Products FS Calibrator 1), are combined by the VITROS 5,1 FS Chemistry System to perform the VITROS dHDL assay for HDL cholesterol.

1.8 Comparison to Predicate Devices

The following tables show similarities and differences between the new and predicate devices identified in Section 1.5 of this summary.

1.8.1 Table 1 New device #1 versus Predicate devices #1 and #2

Attribute	Predicate device #1 VITROS® 950 Chemistry System	Predicate device #2 Bayer ADVIA 1650 Chemistry System	New device #1 VITROS® 5,1 FS Chemistry System
Maximum Throughput	752 tests per hour	1650 tests per hour	845 tests per hour
Maximum Throughput	300 samples per hour	1200 samples per hour	370 samples per hour
Technology/Methodologies	Colorimetric, Rate, Potentiometric, Immunorate	Colorimetric, Potentiometric, Rate and Homogeneous immunoassay.	Chemistry Slides - Colorimetric, Potentiometric, Rate, Immunorate. MicroTip reagents – Endpoint colorimetric and rate, Enzyme-coupled Immunoassay, Homogeneous Turbidimetric Immunoassay, Enhanced Latex Turbidimetric Immunoassay.
Sample Containers Supported	Cups, primary sample collection tubes	Cups, primary sample collection tubes	Cups, primary sample collection tubes
Selective/Discrete Testing	Yes	Yes	Yes
STAT Capability	Yes	Yes	Yes
Sample ID Input	Manual or Bar code	Manual or Bar Code	Manual or Bar Code
On-line Quality Control	Yes	Yes	Yes
Test Panels Available	Yes	Yes	Yes
Bi-directional Computer Interface	Yes	Yes	Yes
Primary Container Sampling	Yes	Yes	Yes
Multiple Lots of Reagents On-Board at One Time	Yes	Not stated	Yes
Reagent Barcode Readers	Yes	Yes	Yes

Comparison Table continued Attribute	Predicate device #1 VITROS® 950 Chemistry System	Predicate device #2 Bayer ADVIA 1650 Chemistry System	New device #1 VITROS® 5,1 FS Chemistry System
Incubator Positions	Rate/Colorimetric = 24 positions, Colorimetric = 27 positions, Potentiometric = 15 positions, and Immunorate/Colorimetric = 26 positions.	221 cuvettes	Chemistry slide incubator = 106 positions MicroTip incubator = 48 positions
Load Master Curve Information	3.5" Diskette	User configurable	CD-ROM
Load Assay Protocol Information	Software	User configurable	CD-ROM
Calibration	Programmable	Programmable	Programmable
Display Calibration Curve	No	Yes	No
Display Calibration Data	Yes	Yes	Yes
Multiple Lots of Calibrator Supported?	Yes	Not stated	Yes
Multiple Calibrations on Each Lot of Calibrator or Reagent?	Yes	Not stated	Yes
On-Analyzer Storage of Reagents	Yes - up to 5 weeks	Yes- average 28 days	Yes - up to 5 weeks for Chemistry slides MicroTip reagents duration dependent on assay
Reagent Packs On-Board	75	46	89 positions for Chemistry Slides, 36 positions for MicroTip reagents and diluents.
Electrolyte Reference Fluid Reservoir Capacity	800 10 µL drops (disposable)	Not applicable	800 10 µL drops (disposable)
Specimen Type	Serum, plasma, urine, CSF	Serum, plasma and urine	Serum, plasma, urine, CSF, whole blood (lyzed off system for HbA1c)

Comparison Table continued Attribute	Predicate device #1 VITROS® 950 Chemistry System	Predicate device #2 Bayer ADVIA 1650 Chemistry System	New device #1 VITROS® 5,1 FS Chemistry System
Operator Interface	Touchscreen, Keyboard, Floppy Diskettes	Touchscreen and Keyboard	Touchscreen, Keyboard, CD
Test Modes	Continuous, Random, STAT	Continuous, Random, STAT	Continuous, Random, STAT
On-Analyzer Sample Capacity	40	200	150 routine samples plus 10 STAT samples
Maximum reagent test capacity	4500 chemistry slides	32,200 tests maximum	Chemistry Slides = 5340 MicroTip reagents = 3600
Periodic Maintenance checks in S/W	Yes	Yes	Yes
Subsystem Performance Tests in S/W	Yes	Yes	Yes
Diagnostics Package in S/W	Yes	Yes	Yes
Sample Status Screen	No	Yes	Yes
Environmental Monitoring	Yes	Yes	Yes
Sample Programming	Yes (Via keyboard and LIS - broadcast download)	Yes (Via keyboard and host computer)	Yes (Via keyboard and LIS - either broadcast download or host query)
Stored sample programs	10,000	Not stated	10,000
Maximum Test per Sample	40	Not stated	40
Result Reporting	Yes	Yes	Yes

Comparison Table continued Attribute	Predicate device #1 VITROS® 950 Chemistry System	Predicate device #2 Bayer ADVIA 1650 Chemistry System	New device #1 VITROS® 5,1 FS Chemistry System
Patient Results On-board	5,000 records	70,000 patient sample records	25,000 records
S/W Quality Control Package	Yes	Yes	Yes
QC Results On-board	12 control fluid files with 160 analyte/control fluid combinations	Not stated	100 control fluid files with 2,190 results per analyte/control fluid combination
Sample Usage per Assay	5 - 11 µL, depending on assay selected	2 - 30 µL, depending on assay selected	2 - 12 µL, depending on assay selected
Sample metering	Disposable Tip	Probe	Disposable Tip
Disposable Tip Loading	Manual Tip Loading	None	On-board supply of 2000 tips, automatically fed.
Minimum Sample Volume (including dead volume)	For a VITROS Microsample cup - 30 µL + 11 µL per assay (worst case) for 1-6 assays, 100 µL + 11 µL per assay (worst case) for 7 or more assays.	From sample cup 30 µL + 50 µL per assay (worst case); collection tube 30 µL + 200 µL per assay	For a VITROS Microsample cup - 30 µL + 11 µL per assay (worst case) for 1-6 assays, 100 µL + 11 µL per assay (worst case) for 7 or more assays.
Addition / Removal of Samples	While running	While running	While running
Clot Detection	Yes	Yes	Yes
Level Sense (sample)	Yes	Yes	Yes
Level Sense (waste)	No	Not applicable	Yes
Waste Capacity	None stated	Requires drain with minimum capacity 6.8 gallons per hour; probes and cuvettes are washed and reused.	Slide waste = 3,780 Chemistry Slides. Other Disposables waste = approximately 1,145 VITROS® VersaTips, 140 VITROS® FS MicroTips, 3 MicroTip trays, and 100 VITROS® FS Cuvettes (or a total of approximately 5.5 pounds).

1.8.2 Table 2 New device #2 versus Predicate device # 3

Device Characteristic	New Device #2: VITROS dHDL assay	Predicate Device #3: Bayer HDL Cholesterol II assay
Basic principle	Homogeneous enzymatic colorimetric test	Homogeneous enzymatic colorimetric test
Reagents	Liquid ready to use	Liquid ready to use
Test Type	Multi-point rate	2-point rate
Instrumentation	VITROS 5,1 FS Chemistry System	Bayer ADVIA 1650 Chemistry System
Sample type	Serum and plasma (Li heparin).	Serum and plasma (Li heparin).
Sample volume	3 µL	5 µL
Incubation time and temperature	Incubation 1: 5 minutes Incubation 2: 3.2 minutes	10 minutes
Incubation Temperature	37°C	37°C

Substantial equivalence of the VITROS 5,1 FS Chemistry System to commercially available predicates, the VITROS 950 Chemistry System and the Bayer ADVIA 1650 Chemistry System, is demonstrated by the feature and functions comparison Table 1.

In order to demonstrate the safe and effective performance of the VITROS 5,1 FS Chemistry System with VITROS Chemistry Products Slides, a representative sample of marker assays was selected to demonstrate key performance characteristics of the system. This performance demonstration provides information for each of the general methodology classes for commercially available VITROS Chemistry Products Slides that can be used to measure various analytes with the VITROS 5,1 FS Chemistry System, including colorimetric endpoint, potentiometric, multipoint rate, multipoint immunorate, and two-point rate methods.

The VITROS Chemistry Products dHDL Reagent Pack and VITROS Chemistry Products Calibrator Kit 19 and VITROS Chemistry Products FS Calibrator 1 are substantially equivalent to the Bayer Direct HDL Cholesterol Method that was cleared by the FDA (K982341) for IVD use.

The relationship between the VITROS dHDL assay and the Bayer Direct HDL Cholesterol II assay, determined by Least Squares linear regression, is:

VITROS dHDL assay = 0.9742 x X – 0.0682 (mg/dL),
with a correlation coefficient of 0.9836,
where X is Bayer Direct HDL Cholesterol II assay.

This relationship was determined from a panel of 107 patient samples.

In addition to the above mentioned correlation study, studies were performed or literature resources were used to determine the precision, expected values, linearity, and specificity of the VITROS dHDL assay, (refer to the VITROS Chemistry Products Reagent Pack Instructions for Use for summaries of the results of these studies).

VITROS Chemistry Products assay	Units	Mean Conc.	Within Day SD	Within Lab SD	Within Lab CV%	No. Observ.	No. Days
AST (Aspartate aminotransferase)	U/L	38	0.5	0.7	1.8	60	10
		200	1.2	2.4	1.2	60	10
CREA (Creatinine)	mg/dL	1.1	0.03	0.03	2.5	60	10
		5.8	0.08	0.10	1.8	60	10
Na+ (Sodium)	mmol/L	119	0.6	1.0	0.8	60	10
		142	0.8	1.2	0.9	60	10
PHYT (Phenytoin)	µg/mL	8.3	0.18	0.32	3.8	60	10
		14.5	0.33	0.46	3.2	60	10
		26.0	0.94	1.20	4.6	60	10
URIC (Uric acid)	mg/dL	4.5	0.04	0.07	1.7	60	10
		10.2	0.08	0.11	1.1	60	10
dHDL (HDL Cholesterol)	mg/dL	49.6	0.92	1.58	3.37	88	22
		67.1	1.38	2.02	3.01	88	22

Table 3 Method Comparison Study Results with VITROS 5,1 FS Chemistry System

Analyte	Slope	Intercept	R	Versus Predicate
AST (Aspartate aminotransferase)	1.00	-5.92	0.996	VITROS 950 System with VITROS Chemistry Products AST Slides
CREA (Creatinine)	0.98	0.04	1.000	VITROS 950 System with VITROS Chemistry Products CREA Slides
PHYT (Phenytoin)	1.02	-0.09	0.997	VITROS 950 System with VITROS Chemistry Products PHYT Slides
Na^+ (Sodium)	1.00	-0.82	0.999	VITROS 950 System with VITROS Chemistry Products Na^+ Slides
URIC (Uric acid)	1.00	0.02	1.000	VITROS 950 System with VITROS Chemistry Products URIC Slides
dHDL (HDL Cholesterol)	0.974	-0.0682	0.984	Bayer ADVIA 1650 System with Bayer Direct HDL Cholesterol II

Table 4 Linearity: Reportable (Dynamic) Range

	VITROS 5,1 FS Chemistry System	Predicate	
AST (Aspartate aminotransferase)	3–750 U/L	3–750 U/L	VITROS 950 System with VITROS Chemistry Products AST Slides
CREA (Creatinine)	0.05–14.00 mg/dL	0.05–14.00 mg/dL	VITROS 950 System with VITROS Chemistry Products CREA Slides
PHYT (Phenytoin)	3.00–40.00 µmol/L	3.00–40.00 µmol/L	VITROS 950 System with VITROS Chemistry Products PHYT Slides
Na^+ (Sodium)	75.0–250.0 mmol/L	75.0–250.0 mmol/L	VITROS 950 System with VITROS Chemistry Products Na^+ Slides
URIC (Uric acid)	0.50–17.00 mg/dL	0.50–17.00 mg/dL	VITROS 950 System with VITROS Chemistry Products URIC Slides
dHDL (HDL Cholesterol)	3.00-100.0 mg/dL	17-90 mg/dL	Bayer ADVIA 1650 System with Bayer Direct HDL Cholesterol II

1.9 Conclusions

The data presented in this pre-market notification demonstrate that the performance of the VITROS 5,1 FS Chemistry System and the VITROS Chemistry Products dHDL assay are substantially equivalent to the cleared predicate devices.

Equivalence to predicates was demonstrated using commercially available reagents along with patient samples.

The data presented in the premarket notification provide a reasonable assurance that the VITROS 5,1 FS Chemistry System and the VITROS dHDL assay are safe and effective for the stated intended uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG - 7 2003

Neil Greenberg, Ph.D.
Manager, Regulatory Affairs
Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, NY 14626-5101

Re: k031924
Trade/Device Name: VITROS 5,1 FS Chemistry System
VITROS Chemistry Products dHDL, Reagent Pack
VITROS Chemistry Products Calibrator Kit 19
VITROS Chemistry Products FS Calibrator 1
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIT; JJE; LBR
Dated: June 20, 2003
Received: June 23, 2003

Dear Dr. Greenberg:

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 predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K031924

Device Names: VITROS 5,1 FS Chemistry System

Intended Use: The VITROS 5,1 FS Chemistry System is intended for use in the *in vitro* quantitative measurement of a variety of analytes of clinical interest, using both VITROS Chemistry Products Slides (colorimetric endpoint, rate, ion-selective electrode, and immunorate methods) and VITROS Chemistry Products MicroTip liquid reagents (spectrophotometric and spectrophotometric immunoassay methods.)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Carol C Benson for Jean Cooper, DVM
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K031924

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Statement of Intended Use

510(k) Number (if known): K031924

Device Names:

1. VITROS Chemistry Products dHDL Reagent Pack
2. VITROS Chemistry Products Calibrator Kit 19
3. VITROS Chemistry Products FS Calibrator 1

Intended Uses:

1. For *in vitro* diagnostic use only. The VITROS dHDL Reagent Pack quantitatively measures HDL cholesterol (HDLC) concentration in serum and plasma. High Density Lipoprotein (HDL) cholesterol is used to evaluate the risk of developing coronary heart disease (CHD). The risk of CHD increases with lower HDL cholesterol concentrations.
2. For *in vitro* diagnostic use only. VITROS Chemistry Products Calibrator Kit 19 is used on the VITROS 5,1 FS Chemistry System in conjunction with VITROS Chemistry Products FS Calibrator 1 to calibrate dHDL.
3. For *in vitro* diagnostic use only. VITROS Chemistry Products FS Calibrator 1 is a saline solution used on the VITROS 5,1 FS Chemistry System in conjunction with VITROS Calibrator Kit 19 to calibrate dHDL.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X (Per 21 CFR 801.109) OR Over-The-Counter Use _____

(Optional Format 1-2-96)

Carol C Benson for Jean Cooper, DVM
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K031924