FEB 5 1999

510(k) Summary

(a) VITROS Folate assay

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: K984166.

1. Submitter name, address, contact

Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, New York 14626-5101
(716) 453-3607

Contact Person: Anne Zavertnik

Date 510(k) prepared: November 18th, 1998

2. Device Name

(a) Folate assay

Trade or Proprietary Name: VITROS Immunodiagnostic Products Folate assay
Common Name: Serum folate assay
Classification Name: Folate assay for the *in vitro* quantitative measurement of folate in human serum and plasma (heparin).

3. Predicate Device

The VITROS Immunodiagnostic Products Folate assay is substantially equivalent to Bio-Rad Quantaphase II Folate Radioassay (K935286).

4. Device Description

The VITROS Immunodiagnostic System uses luminescence as the signal in the quantitative and semi-quantitative determination of selected analytes in human body fluids, commonly serum, plasma and urine. Coated microwells are used as the solid phase separation system.

The system is comprised of three main elements:

1. The VITROS Immunodiagnostic Products range of products, in this case VITROS Immunodiagnostic Products Folate Reagent Pack, VITROS Immunodiagnostic Products Folate Calibrators and the VITROS Immunodiagnostic System. The VITROS Folate Reagent Pack consists of:
   The VITROS Immunodiagnostic Products Folate Reagent Pack 1/2 and the VITROS Immunodiagnostic Products Vitamin B12/Folate Reagent Pack 3

2. The VITROS Immunodiagnostic System - instrumentation, which provides automated use of the immunoassay kits. The VITROS Immunodiagnostic System was cleared for market by a separate 510(k) pre-market notification (K962919).

3. Common reagents used by the VITROS System in each assay. The VITROS Immunodiagnostic Products Signal Reagent and VITROS Immunodiagnostic Products Universal Wash Reagent were cleared as part of the VITROS Immunodiagnostic Products Total T3 510(k) pre-market notification (K984310).

The VITROS System and common reagents are dedicated specifically only for use with the VITROS Immunodiagnostic Products range of immunoassay products.

5. Device Intended Use

The VITROS Folate assay is intended for the *in vitro* quantitative measurement of folate in human serum and plasma (heparin) and whole blood (red cell folate), to aid in the differential diagnosis of anemia.

6. Comparison to Predicate Device

The VITROS Immunodiagnostic Products Folate assay is substantially equivalent to Bio-Rad Quantaphase II Folate Radioassay (predicate device), which was cleared by FDA (K935286) for IVD use.

The relationship between the VITROS Folate assay and the predicate device, determined by Deming's Regression, is:
VITROS Folate assay =0.999 x Bio-Rad Quantaphase II Folate Radioassay + 0.676 ng/mL
Comparisons of the VITROS Folate assay and the predicate device were performed with samples from a variety of clinical categories.

In addition to the studies mentioned above, tests were performed to obtain analytical sensitivity, specificity, precision, dilution and expected values. Refer to the VITROS Folate assay package insert for VITROS Folate assay results.
Table 1 lists the similarities and differences of the device characteristics between the VITROS Folate assay with the predicate device, Bio-Rad Quantaphase II Folate Radioassay.

Table 1 List of the assay characteristics

Device Characteristic	VITROS Folate assay	Predicate Device
Calibration range	0 – 20 ng/ml	0-20 ng/mL
Basic principle	Solid phase assay	Radioassay
Tracer	Enzyme labeled	^{125}Iodine
Instrumentation	VITROS Immunodiagnostic System	Gamma Counter
Sample type	Serum, plasma (heparin)	Serum or plasma (EDTA)
Binding protein	Folate binding protein, purified from bovine milk.	Folate binding protein
Sample volume	53 µL	200 µL
Incubation time and temperature	73 mins at 37 °C	1 hour at room temperature.

7. Conclusions

The data presented in the pre-market notification demonstrate that the VITROS Folate assay performs substantially equivalent to the predicate device, that was cleared by FDA (K935286) for IVD use.

Equivalence was demonstrated using currently commercially available reagents along with patient specimens covering a variety of clinical categories.

The data presented in the premarket notification provide a reasonable assurance that the VITROS Folate assay is safe and effective for the stated intended use.

510(k) Summary, Continued

(b) VITROS Red Cell Folate Pack

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: _____.

1. Submitter name, address, contact

Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, New York 14626-5101
(716) 453-3607

Contact Person: Anne Zavertnik

Date 510(k) prepared: November 18th, 1998

2. Device Name

Trade or Proprietary Name: VITROS Immunodiagnostic Products Red Cell Folate Pack (performed using the Vitros Folate Reagent Pack 1/2, VITROS Vitamin B12/Folate Reagent Pack 3 and the VITROS Red Cell Folate Pack)
Common Name: Red cell folate assay.
Classification Name: Red cell folate assay for the *in vitro* quantification of folate in human whole blood.

3. Predicate Device

The VITROS Immunodiagnostic Products Red Cell Folate assay, is substantially equivalent to Bio-Rad Quantaphase II Folate Radioassay used with the Bio-Rad Red Cell Folate Reagent Pack (K935286).

4. Device Description

The VITROS Immunodiagnostic System uses luminescence as the signal in the quantitative and semi-quantitative determination of selected analytes in human body fluids, commonly serum, plasma and urine. Coated microwells are used as the solid phase separation system.

The system is comprised of three main elements:

1. The VITROS Immunodiagnostic Products (in this case VITROS Immunodiagnostic Products Red Cell Folate Pack, VITROS Immunodiagnostic Products Folate Pack 1/2, VITROS Immunodiagnostic Products Vitamin B12/Folate Reagent Pack 3, VITROS Immunodiagnostic Products Folate Calibrators, which are combined by the VITROS Immunodiagnostic System to perform the VITROS Red Cell Folate assay).

2. The VITROS Immunodiagnostic System - instrumentation, which provides automated use of the immunoassay kits. The VITROS Immunodiagnostic System was cleared for market by a separate 510(k) pre-market notification (K962919).

3. Common reagents used by the VITROS System in each assay. The VITROS Immunodiagnostic Products Signal Reagent and VITROS Immunodiagnostic Products Universal Wash Reagent were cleared as part of the VITROS Immunodiagnostic Products Total T3 510(k) pre-market notification (K984310).

The VITROS System and common reagents are dedicated specifically only for use with the VITROS Immunodiagnostic Products range of immunoassay products.

5. Device Intended Use

The Vitros Red Cell Folate Pack is intended for use in whole blood sample preparation to allow the *in vitro* quantitative measurement of red cell folate using the VITROS Immunodiagnostic System.

6. Comparison to Predicate Device

The VITROS Immunodiagnostic Products Red Cell Folate assay, is substantially equivalent to Bio-Rad Quantaphase II Folate Radioassay (predicate device), used with the Bio-Rad Red Cell Folate Reagent Pack, that was cleared by FDA (K935286) for IVD use.

The relationship between the VITROS Red Cell Folate assay and the predicate device, determined by Deming's Regression, is:
VITROS Red Cell Folate assay =1.17 x Bio-Rad Quantaphase II Folate assay (used with the Bio-Rad Red Cell Folate Reagent Pack) + 4.0 (ng/mL)
Comparisons of the VITROS Red Cell Folate assay and the predicate device were performed with samples from a variety of clinical categories.
Although there was a good correlation between the assays (r = 0.979), the VITROS assay showed an overall 17% positive bias. The results reflect true numerical differences for red cell folate measurement between the VITROS and Bio-Rad Quantaphase II assays.

In addition to the studies mentioned above, tests were performed to obtain precision, linearity and expected values. Refer to the VITROS Red Cell Folate Pack package insert for VITROS Red Cell Folate assay results.

Table 1 lists the similarities and differences of the device characteristics between the VITROS Red Cell Folate assay with the predicate device, Bio-Rad Quantaphase II Folate assay (used with the Bio-Rad Red Cell Folate Reagent Pack).

Table 1 List of the assay characteristics

Device Characteristic	VITROS Red Cell Folate assay	Predicate Device
Calibration range	0 – 20 ng/ml	0 – 20 ng/ml
Basic principle	Solid phase assay	Radioassay
Tracer	Enzyme labeled	^{125}I
Instrumentation	VITROS Immunodiagnostic System	Gamma Counter
Sample type	Whole blood (EDTA or heparin)	Whole blood (EDTA)
Binding Protein	Folate binding protein	Folate binding protein
Sample volume	53 µL	200 µL
Incubation time and temperature	90 minutes at room temperature (whole blood preparation); 73 minutes at 37° C (folate assay)	90 minutes at room temperature (whole blood preparation); 60 minutes at room temperature (folate assay).

7. Conclusions

The data presented in the pre-market notification demonstrate that the VITROS Red Cell Folate assay performs substantially equivalent to the predicate, that was cleared by FDA (K935286) for IVD use.

Equivalence was demonstrated using currently commercially available reagents along with patient specimens covering a variety of clinical categories.

The data presented in the premarket notification provide a reasonable assurance that the VITROS Red Cell Folate assay is safe and effective for the stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 5 1999

Ms. Anne Zavertnik
Regulatory Affairs Associate
Ortho-Clinical Diagnostics
A Johnson & Johnson Company
100 Indigo Creek Drive
Rochester, New York 14626-5101

Re: K984166
Trade Name: VITROS Immunodiagnostic Products Folate Assay
Regulatory Class: II Product Code: CGN
II JIS
Dated: January 6, 1999
Received: January 7, 1999

Dear Ms. Zavertnik:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Chapter 1 – Summary Information

Indications for Use Statement

510(k) Number (if known)

Device Name:

1. VITROS Immunodiagnostic Products Folate Reagent Pack 1/2
2. VITROS Immunodiagnostic Products Vitamin B12/Folate Reagent Pack 3
3. VITROS Immunodiagnostic Products Folate Calibrators
4. VITROS Immunodiagnostic Products Red Cell Folate Pack

Indications for Use:

1. & 2. The VITROS Immunodiagnostic Products Folate Reagent Pack 1/2 and the VITROS Immunodiagnostic Products Vitamin B12/Folate Reagent Pack 3 - for the *in vitro* quantitative measurement of folate in human serum and plasma (heparin) and whole blood (red cell folate), to aid in the differential diagnosis of anemia.

3. The VITROS Immunodiagnostic Products Folate Calibrators - for *in vitro* use in the calibration of the VITROS Immunodiagnostic System for the quantitative measurement of folate in human serum and plasma (heparin).

4. The VITROS Immunodiagnostic Products Red Cell Folate Pack - for whole blood sample preparation, to allow the *in vitro* quantitative measurement of red cell folate using the VITROS Immunodiagnostic System.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K984166

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

(Optional Format 1-2-96)