



Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

JAN - 7 1998

David Johnston  
TAI Technical Director  
TRACE America, Inc.  
7260 Northwest 58th Street  
Miami, Florida 33166

Re: K973869  
TRACE Reagent Line for the Cobas Mira  
Regulatory Class: II  
Product Code: CKA, JFJ, CDQ, CEK, CGX, CHH, CIG, CIT,  
JGY, JHB, JIY, JMO, KHS  
Dated: October 24, 1997  
Received: October 28, 1997

Dear Mr. Johnston:

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 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 (Pre-market 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.

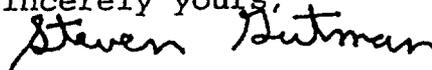
Page 2

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/dsmamain.html>".

Sincerely yours,



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

510(k) Number (if known): K97 3869

Device Name: TRACE REAGENT LINE FOR THE COBAS MIRA

Indications for Use:

Intended for the the In Vitro, quantitative determination of ALT (L-Alanine;2-Oxoglutarate Aminotransferase EC2.6.1.2) in human serum on the Cobas MIRA ® clinical chemistry system.

This alanine aminotransferase (ALT/SGPT) test system is a device intended to measure the activity of the enzyme alanine aminotransferase (ALT) (also known as a serum glutamic pyruvic transaminase or SGPT) in serum and plasma. Alanine aminotransferase measurements are used in the diagnosis and treatment of certain liver diseases (e.g. viral hepatitis and cirrhosis) and heart diseases. CFR 862.1030

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Alt On AWM  
(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number K97 3869

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

510(k) Number (if known): K97 3869

Device Name: TRACE REAGENT LINE FOR THE COBAS MIRA

Indications for Use:

Intended for the the In Vitro, quantitative determination of ~~α~~AMYLASE (1,4-~~α~~- D glucan glucanohydrolase EC3.2.1.1) in human serum and urine on the Cobas MIRA ® clinical chemistry system.

This Amylase test system is a device intended to measure the activity of the enzyme Amylase in serum and urine . Amylase measurements are used primarily for the diagnosis and treatment of pancreatitis (inflammation of the pancreas) CFR 862.1070

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use   
(Per 21 CFR 801.109)

OR Over-The-Counter Use

(Optional Format 1-2-96)

  
(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number K973869

510(k) Number (if known): K97 3869

Device Name: TRACE REAGENT LINE FOR THE COBAS MIRA

Indications for Use:

Intended for the the In Vitro, quantitative determination of AST (Aspartate aminotransferase EC2.6.1.1) in human serum on the Cobas MIRA® clinical chemistry system.

This "aspartate aminotransferase (AST/SGOT) test system is a device intended to measure the activity of the enzyme aspartate aminotransferase (AST) (also known as a serum glutamic oxaloacetic transferase or SGOT) in serum and plasma. Aspartate aminotransferase measurements are used in the diagnosis and treatment of certain types of liver and heart disease." CFR 862.1100

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Concurrence of CDRH; Office of Device Evaluation (ODE) .....

Prescription Use    
 (Per 21 CFR 801.109)

OR Over-The-Counter Use

(Optional Format 1-2-96)

  
510(k) Number 97 3869

510(k) Number (if known): K97 3869

Device Name: TRACE REAGENT LINE FOR THE COBAS MIRA

Indications for Use:

Intended for the the In Vitro, quantitative determination of Direct Bilirubin in human serum on the Cobas MIRA ® clinical chemistry system.

This "Direct Bilirubin test system is a device intended to measure the levels of bilirubin (direct) in plasma or serum. Measurements of levels of bilirubin, an organic compound formed during the normal and abnormal destruction of red blood cells, if used in the diagnosis and treatment of the liver, hemolytic hematological, and metabolic disorders, including hepatitis and gall bladder block." CFR 862.1110

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use    
 (Per 21 CFR 801.109)

OR Over-The-Counter Use

(Optional Format 1-2-96)

  
Division Sign-Off  
Division of Clinical Laboratory Devices  
510(k) Number K97 3869

510(k) Number (if known): K97 3869

Device Name: TRACE REAGENT LINE FOR THE COBAS MIRA

Indications for Use:

Intended for the the In Vitro, quantitative determination of Total Bilirubin in human serum on the Cobas MIRA ® clinical chemistry system.

This "Total Bilirubin test system is a device intended to measure the levels of bilirubin (Total) in plasma or serum. Measurements of levels of bilirubin, an organic compound formed during the normal and abnormal destruction of red blood cells, if used in the diagnosis and treatment of the liver, hemolytic hematological, and metabolic disorders, including hepatitis and gall bladder block." CFR 862.1110

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use

(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

  
(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number K97 3869

510(k) Number (if known): K97 3869

Device Name: TRACE REAGENT LINE FOR THE COBAS MIRA

Indications for Use:

Intended for the the In Vitro, quantitative determination of Calcium in human serum or urine on the Cobas MIRA ® clinical chemistry system.

This "Calcium test system is a device intended to measure the total calcium level in serum. Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms" CFR 862.1145

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use              
(Per 21 CFR 801.109)

OR Over-The-Counter Use            

(Optional Format 1-2-96)

  
(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) number K973869

510(k) Number (if known): K97 3869

Device Name: TRACE REAGENT LINE FOR THE COBAS MIRA

Indications for Use:

Intended for the the In Vitro, quantitative determination of Total CO2 in human serum on the Cobas MIRA ® clinical chemistry system.

This " bicarbonate/ carbon dioxide test system is a device intended to measure the total bicarbonate/carbon dioxide plasma, serum and whole blood. Bicarbonate/carbon dioxide measurements are used in the diagnosis and treatment of numerous potentially serious disorders associated with changes in body acid base balance." CFR 862.1160

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use              
(Per 21 CFR 801.109)

OR

Over-The-Counter Use           

(Optional Format 1-2-96)

  
(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number K973869

510(k) Number (if known): K97 3869

Device Name: TRACE REAGENT LINE FOR THE COBAS MIRA

Indications for Use:

Intended for the the In Vitro, quantitative determination of Chloride in human serum on the Cobas MIRA ® clinical chemistry system.

This " Chloride test system is a device intended to measure the Chloride in plasma, serum, sweat and urine. Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis. " CFR 862.1170

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use              
(Per 21 CFR 801.109)

OR Over-The-Counter Use            

(Optional Format 1-2-96)

  
(Division Sign-Off)  
Div:             
510(k) Number K973869  
Laboratory Devices

510(k) Number (if known): K97 3869

Device Name: TRACE REAGENT LINE FOR THE COBAS MIRA

Indications for Use:

Intended for the the In Vitro, quantitative determination of Cholesterol in human serum on the Cobas MIRA ® clinical chemistry system.

This " Cholesterol test system is a device intended to measure the Cholesterol in plasma and serum. Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders. " CFR 862.1175

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Concurrence of CDRH, Office of Device Evaluation (ODE) \_\_\_\_\_

Prescription Use  \_\_\_\_\_  
(Per 21 CFR 801.109)

OR Over-The-Counter Use  \_\_\_\_\_

(Optional Format 1-2-96)

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Division of Clinical Laboratory Devices  
510(k) Number K97 3869

510(k) Number (if known): K97 3869

Device Name: TRACE REAGENT LINE FOR THE COBAS MIRA

Indications for Use:

Intended for the the In Vitro, quantitative determination of Creatinine in human serum and urine on the Cobas MIRA ® clinical chemistry system.

This " Creatinine test system is a device intended to measure the Creatinine levels in plasma and urine. Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and a calculation basis for measuring other urine analytes. " CFR 862.1225

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use              
(Per 21 CFR 801.109)

OR Over-The-Counter Use            

(Optional Format 1-2-96)

  
Device number K973869

510(k) Number (if known): K97 3869

Device Name: TRACE REAGENT LINE FOR THE COBAS MIRA

Indications for Use:

Intended for the the In Vitro, quantitative determination of Glucose in human serum and urine on the Cobas MIRA ® clinical chemistry system.

This " Glucose test system is a device intended to measure the Glucose levels in blood and other body fluids. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia , idiopathic hypoglycemia and pancreatic islet cell carcinoma. " CFR 862.1360

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Concurrence of CDRH, Office of Device Evaluation (ODE) .....

Prescription Use    
 (Per 21 CFR 801.109)

OR Over-The-Counter Use

(Optional Format 1-2-96)

  
(Division Sign-Off)  
Division  
510(k) Number K973869

510(k) Number (if known): K97 3869

Device Name: TRACE REAGENT LINE FOR THE COBAS MIRA

Indications for Use:

Intended for the the In Vitro, quantitative determination of Iron in human serum on the Cobas MIRA ® clinical chemistry system.

This " Iron (non-heme) test system is a device intended to measure Iron (non-heme) in serum and plasma. Iron (non-heme) measurements are used in the diagnosis and treatment of diseases such as iron deficiency anemia , hemochromatosis ( a disease associated with widespread deposit in the tissues of two iron containing pigments, hemosiderin and hemofuscin, and characterized by pigmentation of the skin) and chronic renal disease. " CFR 862.1410

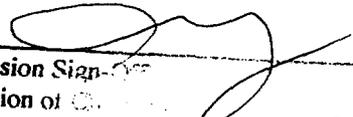
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use   
(Per 21 CFR 801.109)

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510(k) Number K973869

(Optional Format 1-2-96)

510(k) Number (if known): K97 3869

Device Name: TRACE REAGENT LINE FOR THE COBAS MIRA

Indications for Use:

Intended for the the In Vitro, quantitative determination of Magnesium in human serum and urine on the Cobas MIRA ® clinical chemistry system.

This " Magnesium test system is a device intended to measure magnesium levels in serum and plasma. Magnesium measurements are used in the diagnosis and treatment of hypomagnesemia (abnormally low plasma levels of magnesium) and hypermagnasemia (abnormally high levels of magnesium). " CFR 862.1495

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

  
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Division of \_\_\_\_\_  
510(k) Number K97 3869

510(k) Number (if known): K97 3869

Device Name: TRACE REAGENT LINE FOR THE COBAS MIRA

Indications for Use:

Intended for the the In Vitro, quantitative determination of Inorganic Phosphorus in human serum or urine on the Cobas MIRA ® clinical chemistry system.

This " Phosphorus (inorganic) test system is a device intended to measure inorganic phosphorus in serum, plasma and urine. Measurements of phosphorus (inorganic) are used in the diagnosis and treatment of various disorders, including parathyroid gland and kidney diseases , and vitamin D imbalance. " CFR 862.1580

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use   
(Per 21 CFR 801.109)

OR Over-The-Counter Use

(Optional Format 1-2-96)

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Division Sign-Off  
Division of Clinical Laboratory Devices  
510(k) Number K97 3869

510(k) Number (if known): K97 3869

Device Name: TRACE REAGENT LINE FOR THE COBAS MIRA

Indications for Use:

Intended for the the In Vitro, quantitative determination of Total Protein in human serum on the Cobas MIRA ® clinical chemistry system.

This " Total Protein test system is a device intended to measure Total protein(s) in serum or plasma. Measurements obtained by this device are used in the diagnosis and treatment of a variety of diseases involving the liver, kidney or bone marrow as well as other metabolic or nutritional disorders " CFR 862. 1635

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use

(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

  
510(k) Number K97 3869  
Laboratory Devices

510(k) Number (if known): K97 3869

Device Name: TRACE REAGENT LINE FOR THE COBAS MIRA

Indications for Use:

Intended for the the In Vitro, quantitative determination of Triglycerides in human serum on the Cobas MIRA ® clinical chemistry system.

This " Triglyceride test system is a device intended to measure Triglyceride (neutral fat) in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism, or various endocrine disorders. " CFR 862.1705

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Concurrence of CDRH, Office of Device Evaluation (ODE)

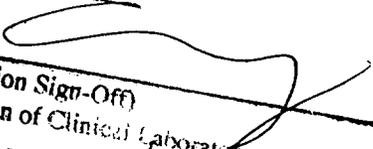
Prescription Use

OR

Over-The-Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

  
(Division Sign-Off)  
Division of Clinical Laboratory Services  
510(k) Number K973869

510(k) Number (if known): K97 3869

Device Name: TRACE REAGENT LINE FOR THE COBAS MIRA

Indications for Use:

Intended for the the In Vitro, quantitative determination of Urea Nitrogen in human serum or urine on the Cobas MIRA ® clinical chemistry system.

This " urea nitrogen test system is a device intended to measure urea nitrogen (an end product of nitrogen metabolism) in whole blood, serum or plasma. Measurements obtained by this device are used in the diagnosis and treatment of certain renal and metabolic diseases. " CFR 862.1770

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use

(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

  
(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number K97 3869

510(k) Number (if known): K97 3869

Device Name: TRACE REAGENT LINE FOR THE COBAS MIRA

Indications for Use:

Intended for the the In Vitro, quantitative determination of Unbound Iron-Binding Capacity (UIBC) in human serum on the Cobas MIRA ® clinical chemistry system.

This " Iron-binding capacity test system is a device intended to measure Iron-binding capacity in serum. Iron-binding capacity measurements are used in the diagnosis and treatment of anemia. " CFR 862.1415

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓  
(Per 21 CFR 801.109)

OR Over-The-Counter Use    

(Optional Format 1-2-96)

  
(Division Sign-Off)  
Division of Clinical Laboratory  
510(k) Number K973869

510(k) Number (if known): K97 3869

Device Name: TRACE REAGENT LINE FOR THE COBAS MIRA

Indications for Use:

Intended for the the In Vitro, quantitative determination of Uric Acid in human serum or urine on the Cobas MIRA ® clinical chemistry system.

This " Uric Acid test system is a device intended to measure uric acid in serum, plasma or urine. Measurements obtained by this device are used in the diagnosis and treatment of numerous renal and metabolic disorders, including renal failure, gout, leukemia, psoriasis, starvation or other wasting conditions, and of patients receiving cytotoxic drugs. " CFR 862.1775

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use

(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

*[Signature]*  
Division of Clinical Laboratory Devices  
510(k) Number K973869