DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Vital Diagnostics
c/o Melita Lambiris
Technical and Regulatory Affairs Manager
189-199 Browns Road, Noble Park
Victoria, 3174, Australia

DEC 15 2010

Re: k100060
Trade/Device Name: EON 100 Chemistry Analyzer with Ion Selective Electrode (ISE), EON Amylase Reagent, EON Albumin Reagent, EON Bicarbonate Reagent, EON ISE Reagent Pack, EON Uric Acid Reagent, EON Calibrator Kit, EON Carbon Dioxide Calibrator

Regulation Number: 21 CFR 862.1070
Regulation Name: Amylase test system
Regulatory Class: Class II
Product Code: JFJ, JJE, CIX, KHS, JGS, CEM, CGZ, KNK, JIX, JIT
Dated: December 2, 2010
Received: December 6, 2010

Dear Ms. Lambiris

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 advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

DEC 15 2010

510(k) Number (if known): k100060

Device Name: Eon 100 Chemistry Analyzer with ISE

Indications for Use:

The Eon 100 is a discrete photometric chemistry analyzer for clinical use. It is a device intended for the in-vitro, spectrophotometric determination of general chemistry assays. The Eon 100 has replaceable parts, automated maintenance monitoring and backup of both patient and system data.

The Eon 100 Chemistry Analyzer is intended to be used to assist the clinician with the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease.

The Eon 100 includes an optional Ion Selective Electrodes (ISE) module for the measurement of sodium, potassium and chloride in serum and plasma.

The Eon 100 is for in vitro diagnostic use only.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Carol C. Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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Indications for Use Form

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510(k) Number (if known): k100060

Device Name: Eon Amylase Reagent

Indications for Use:

An amylase test system is a device intended to measure the quantitative activity of the enzyme amylase in serum and plasma on the EON 100 Chemistry Analyzer. Amylase measurements are used primarily for the diagnosis and treatment of pancreatitis (inflammation of the pancreas).

Prescription Use ___x___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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510(k) Number (if known): k100060

Device Name: Eon Albumin Reagent

Indications for Use:

An albumin test system is a device intended to quantitatively measure the albumin concentration in serum and plasma on the EON 100 Chemistry Analyzer. Albumin measurements are used in the diagnosis and treatment of numerous diseases involving primarily the liver or kidneys.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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510(k) Number (if known): k100060

Device Name: Eon Bicarbonate Reagent

Indications for Use:

A bicarbonate/carbon dioxide test system is a device intended to quantitatively measure bicarbonate/carbon dioxide in serum and plasma on the EON 100 Chemistry Analyzer. Bicarbonate/carbon dioxide measurements are used in the diagnosis and treatment of numerous potentially serious disorders associated with changes in body acid-base balance.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Device Name: Eon ISE Reagent Pack

Indications for Use:

Sodium
A sodium test system is a device intended to quantitatively measure sodium in serum and plasma on the EON 100 Chemistry Analyzer. Measurements obtained by this device are used in the diagnosis and treatment of aldosteronism (excessive secretion of the hormone aldosterone), diabetes insipidus (chronic excretion of large amounts of dilute urine, accompanied by extreme thirst), adrenal hypertension, Addison's disease (caused by destruction of the adrenal glands), dehydration, inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte imbalance.

Potassium
A potassium test system is a device intended to quantitatively measure potassium in serum and plasma on the EON 100 Chemistry Analyzer. Measurements obtained by this device are used to monitor electrolyte balance in the diagnosis and treatment of diseases conditions characterized by low or high blood potassium levels.

Chloride
A chloride test system is a device intended to quantitatively measure the level of chloride in serum and plasma on the EON 100 Chemistry Analyzer. Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis

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

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Device Name: Eon Total Protein Reagent

Indications for Use:

A Total protein test system is a device intended to quantitatively measure total protein(s) in serum and plasma on the EON 100 Chemistry Analyzer. 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.

Prescription Use ___x___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Device Name: Eon Uric Acid Reagent

Indications for Use:

A Uric acid test system is a device intended to quantitatively measure uric acid in serum and plasma on the EON 100 Chemistry Analyzer. 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.

Prescription Use ___x___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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510(k) Number (if known): k100060

Device Name: Eon Calibrator Kit

Indications for Use:

The Eon Calibrator Kit is a device intended for medical purposes for use in a test system to establish points of reference for albumin, total protein, and uric acid on the EON 100 Chemistry Analyzer that are used in the determination of values in the measurement of substances in human specimens.

Prescription Use ___x___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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510(k) Number (if known): k100060

Device Name: Eon Carbon Dioxide Calibrator

Indications for Use:

The Eon Carbon Dioxide Calibrator is a device intended for medical purposes for use in the Eon Carbon Dioxide Reagent assay on the EON 100 Chemistry Analyzer to establish points of reference that are used in the determination of values in the measurement of carbon dioxide in serum and plasma.

Prescription Use ___x___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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