DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Päivi Sormunen
Vice President of Quality, Regulatory and Compliance
Thermo Electron Corp.
Ratastie 2
PO Box 100
FIN-01621 Vantaa
Finland

AUG - 8 2006

Re: k061107
Trade/Device Name: DPC T60i and DPC T60i Kusti Clincal Chemistry Analyzer and associated assays
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: CFR, CGZ, CEM, JGS, JIX, JJY, JJE
Dated: June 30, 2006
Received: July 10, 2006

Dear Päivi Sormunen:

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 (240) 276-0484. 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/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, 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

510(k) Number (if known): k061107

Device Name: DPC T60i and DPC T60i Kusti Clinical Chemistry Analyzer and associated assays

Indications For Use:

The DPC T60i and DPC T60i Kusti Clinical Chemistry Analyzers are fully automated random access analyzers for in-vitro diagnostic use with clinical laboratory assays validated for use on these instrument platforms, including an ISE unit with Na+, K+ and Cl- electrodes.

The DPC T60 Glucose (HK) test system with associated Calibrators and Controls is intended for quantitative in-vitro diagnostic determination of glucose in serum or plasma using the DPC T60i and DPC T60i Kusti Clinical Chemistry Analyzers. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

The DPC ISE Micro Volume Chloride, Potassium and Sodium Electrodes with associated Calibrators are intended for quantitative in-vitro diagnostic determination of Chloride, Potassium and Sodium in serum or plasma using the DPC T60i and DPC T60i Kusti Clinical Chemistry Analyzers.

Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders.

Potassium measurements monitor electrolyte balance and in the diagnosis and treatment of diseases conditions characterized by low or high blood potassium levels.

Sodium measurements are used in the diagnosis and treatment diseases involving electrolyte imbalance.

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

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

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

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K061107