DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 27 2007

Thermo Electron Oy
c/o Mr. Päivi Sormunen
Vice President of Industrial Solutions
and QRC
Ratastie 2, P.O. Box 100
Vantaa, Finland 01621

Re: k063838
Trade Name: Lipoprotein(a), Lipoprotein(a) Calibrator, Lipoprotein(a) Control, Lipoprotein(a) Control High
Regulation Number: 21 CFR 866.5600
Regulation Name: Low-density lipoprotein immunological test system.
Regulatory Class: Class II
Product Code: DFC, JIT, JJY
Dated: September 19, 2007
Received: September 21, 2007

Dear Mr. 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) 276-0490. 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 (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
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): k063838

Device Names: **Lipoprotein(a)**
Lipoprotein(a) Calibrator
Lipoprotein(a) Control
Lipoprotein(a) Control High

Indications for Use:
For the *in vitro* quantitative determination of the Lipoprotein(a) in human serum, Li-heparin plasma and EDTA plasma on T60 instruments.
Measurement of low-density lipoprotein in serum may aid in the diagnosis of disorders of lipid (fat) metabolism and help to identify specific populations at risk from cardiovascular diseases

Lipoprotein(a) Calibrator is used as a calibrator for quantification of Lipoprotein(a) in serum and plasma by immunoturbidimetry with T60 instruments using methods defined by Thermo Electron Oy

For in vitro diagnostic use on T60 instrument. Lipoprotein(a) Control is intended to be used as an assayed control serum to monitor precision of Lipoprotein(a) test defined by Thermo Electron Oy

For in vitro diagnostic use on T60 instrument. Lipoprotein(a) Control High is intended to be used as an assayed control serum to monitor precision of Lipoprotein(a) test defined by Thermo Electron Oy.

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)

Carol C. Benson

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

K063838