DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG - 8 2007

Thermo Electron Scientific OY
c/o Päivi Sormunen
Vice President of Reagent Business Development and QRC
Clinical Diagnostics Finland
Ratastie 2, P.O. Box 100
FI-01621 Vantaa
Finland

Re: k063086
Trade/Device Name: Transferrin, Specical Calibrator, Specitrol Control and Specitrol High Control
Regulation Number: 21 CFR 866.5880
Regulation Name: Transferrin immunological test system
Regulatory Class: Class II
Product Code: DDG, JJY, JIX
Dated: June 27, 2007
Received: July 02, 2007

Dear Päive 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 the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); 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) 276-0450. 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 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Robert L. Becker, Jr., M.D., Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k063086

Device Name: Transferrin
Specical calibrator
Specitrol control
Specitrol High control

Indications For Use:

Transferrin

The transferrin test system is intended for the quantitative in-vitro diagnostic determination of transferrin in serum or plasma using T60 Clinical chemistry Analyzers. Measurement of transferrin levels aids in the diagnosis of malnutrition, acute inflammation, acute infection and iron deficiency anemia.

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)

Maria M Chan
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K063086

SpeciCal
For in vitro diagnostic use on T60 analyzer. SpeciCal protein calibrator is used as a stock calibrator for both quantification of specific proteins in serum and plasma by immunoturbidimetry and for antigen excess detection using methods defined by Thermo Electron Oy

SpeciTrol
For in vitro diagnostic use on T60 analyzer. SpeciTrol is intended to be used as an assayed control serum to monitor precision of specific protein tests defined by Thermo Electron Oy

Specitrol High
For in vitro diagnostic use on T60 analyzer. Specitrol High is intended to be used as an assayed control serum to monitor precision of specific protein tests defined by Thermo Electron Oy