K971709

JUN 16 1997

MONOBIND, INC.

May. 7, 97

510(k) Summary

Dear Sir:

Monobind Inc. , registration number 2020726, plans to introduce into commercial distribution an enzymeimmunoassay (EIA) kit for the determination of total thyroxine (T4) in human serum or plasma.

The proprietary name is Total Thyroxine (T4) Microplate EIA and the usual name is T4 EIA. This device classification name is - enzyme immunoassay, non-radiolabeled, total thyroxine - product code 75KLI (per 21 CRF section 862.1700).

This device is substantially equivalent to the Monobind total thyroxine (T4) coated tube radioimmunoassay (RIA), which predicates the new device.

The contact individual for this submission is Dr. Frederick R. Jerome.

The Monobind microplate EIA utilizes anti-thyroxine antibody immobilized on the surface of plastic wells of a microtiterplate. Specimens, calibrators or controls are then added followed by the enzyme-T4 conjugate. A competition reaction results between the native thyroxine in the sample and the added enzyme-T4 conjugate for a limited number of antibody combining sites. After the completion of the incubation period, the enzyme-T4 conjugate is separated from unreacted material by decantation. The activity of the enzyme on the well is quantitated by reaction with suitable substrate to produce color.

The intended use of the device: The quantitative determination of total thyroxine concentration in human serum or plasma by a microplate enzymeimmunoassay.

The technological characteristics of the new device compared to the predicate device are essentially identical. This includes the use of the same anti-thyroxine antibody (coated on a plastic surface), identically prepared calibrators, sample size and the composition of the tracer buffer. The sole difference resides in the use of an enzyme tracer compared to a radioisotope.

Substantial equivalency was based on clinical comparison (linear regression), using 131 specimens from hypothyroid, euthyroid and hyperthyroid populations. The mean values for reference method (coated tube RIA) and this method (microplate EIA) are 8.07 and 8.06 respectively. The equation to a straight line (y= 0.39 + 0.952) and correlation coefficient (0.934) indicates good method agreement.

In addition recovery data demonstrated an average recovery of 101.1% when exogenous added thyroxine was introduced into human serum specimens. Similarly, linearity studies showed an average 101.2% when a specimen was diluted and compared to the dose response curve.

729 West 16th Street , Costa Mesa , CA (USA) 92627 Phone: (714) 642-4830 FAX: (714) 650-8459

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 16 1997

Dr. Frederick R. Jerome
Monobind, Inc.
729 West 16th Street
Costa Mesa, California 92627

Re: K971709
Total Throxine Microplate EIA (225-300)
Regulatory Class: II
Product Code: KLI
Dated: May 7, 1997
Received: May 8, 1997

Dear Dr. Jerome:

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 (Premarket 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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.

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 Gutman

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

Indications for Use Statement

510(k) Number (if known): K971709

Device Name: Total Thyroxine (T4) Microplate EIA

The quantitative determination of total thyroxine concentration in human serum or plasma by a microplate enzymeimmunoassay.Measurements obtained from this device are used in the diagnosis and treatment of thyroid diseases.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K971709

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109) (Optional Folmat 1-2-96)