FEB 4 1998

K980088

MONOBIND, INC.

Jan. 7, 98

510(k) Summary

Dear Sir:

Monobind Inc., registration number 2020726, plans to introduce into commercial distribution an enzymeimmunoassay (EIA) kit for the assessment of unsaturated thyroid hormone binding sites in human serum or plasma.

The proprietary name is T-Uptake (TU) Microplate EIA and the usual name is T-Uptake EIA. This device classification name is - Triiodothyronine (T3) uptake test system, - product code KHQ (per 21 CRF section 862.1715).

This device is substantially equivalent to the Monobind T3 Uptake radioassay (RA), which predicates the new device.

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

The Monobind microplate EIA utilizes limited amount of 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 and thyroxine. The endogenous binding proteins of the sample react with the added thyroxine, but not with the enzyme conjugate. This leads to a higher binding of the enzyme conjugate to the antibody combining sites immobilized on the well as the binding capacity of the specimen increases. 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 employment of several serum references of known unsaturated thyroid hormone binding capacity permits construction of a graph of absorbance and concentration. From comparison to the dose response curve, an unknown specimen's absorbance can be correlated with thyroid hormone binding capacity

The intended use of the device: The Measurement of the Total Amount of Binding Sites Available for the Thyroid Hormones in Human Serum or Plasma by a Microplate Enzyme Immunoassay.

The technological characteristics of the new device compared to the predicate device are essentially identical. This includes identically prepared calibrators, and the saturation of binding proteins with exogenously added thyroid hormone. Main differences reside in the use of an enzyme tracer compared to a radioisotope, T4 versus T3 as the saturating thyroid hormone and antibody to pick up the unreacted thyroid hormones versus denatured albumin in the radioassay.

Substantial equivalency was based on clinical comparison (linear regression), using 120 specimens from hypothyroid, pregnant, euthyroid and hyperthyroid populations. The mean values for reference method (radioassay) and this method (microplate EIA) are 29.0 and 29.3 respectively. The equation to a straight line (y= 1.58 + 0.956) and correlation coefficient (0.972) indicates good method agreement.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 4 1998

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

Re: K980088
T-Uptake Microplate EIA
Regulatory Class: II
Product Code: KHQ
Dated: January 8,1998
Received: January 9, 1998

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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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): _____

Device Name: T-Uptake Microplate EIA

The Measurement of the Total Amount of Binding Sites Available for the Thyroid Hormones in Human Serum or Plasma by a Microplate Enzyme Immunoassay. Measurements obtained from this device are used in the diagnosis and treatment of thyroid diseases.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K950088

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Optional Folmat 1-2-96)