



MONOBIND, INC.

May 14, 97

K 971835

JUL - 3 1997

510(k) Summary

Dear Sir:

Monobind Inc., registration number 2020726, plans to introduce into commercial distribution an ELISA kit for the determination of thyroglobulin autoantibodies in human serum or plasma.

The proprietary name is Anti-Thyroglobulin (Tg) Microplate ELISA and the usual name is Anti-Tg ELISA. This device classification name is - thyroid autoantibody immunological test system - product code DDC (per 21 CFR section 866.5870).

This device is substantially equivalent to the Biomerica anti-thyroglobulin ELISA test, which predicates the new device.

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

The Monobind method is based on ELISA technology utilizing the streptavidin-biotin reaction to effect separation. Upon mixing biotinylated thyroglobulin antigen, and a serum containing the autoantibody (anti-Tg), reaction results between the biotinylated thyroglobulin antigen and the antibodies to form an immune complex. Simultaneously, the complex is deposited to the well through the high affinity reaction of streptavidin, coated on the well, and biotinylated thyroglobulin antigen. After incubation is complete, decantation or aspiration separates the unbound components. The enzyme linked species specific antibody (anti-h-IgG) is then added to the microwells. The anti-h-IgG enzyme conjugate that binds to the immobilized immune complex in a second incubation are separated from unreacted material by a wash step. The enzyme activity in this fraction is directly proportional to the antibody concentration in the specimen. By utilizing several different serum references of known antibody activity, a reference curve can be generated from which the antibody activity of an unknown can be ascertained.

The intended use of the device: The quantitative determination of thyroglobulin (Tg) autoantibodies in human serum or plasma by a microplate enzyme immunoassay.

The technological characteristics of the new device compared to the predicate device are very similar. This includes ELISA technology with highly purified thyroglobulin antigen, and diluted human serum prepared calibrators (standardized against the same International reference material 1st IRP 65/93). A difference lies in the use of anti-h-IgG - HRP (Monobind method) versus HRP-Protein A (Biomerica method) to expose the antibody activity on the solid phase. However, both reagents' function is to detect anti-h-IgG on the solid phase. The enzyme and substrate systems are the same.

Substantial equivalency was based on clinical comparison (linear regression), using 82 biological specimens from normal and disease states populations. The disease states included; Hashimoto's thyroiditis, Graves Disease, thyroid nodules as well as thyroid carcinoma. The mean values for reference method and this method are 419.2 IU/ml and 415.6 IU/ml respectively. The equation to a straight-line [$y = 9.79 + 0.969(x)$] and correlation coefficient (0.995) indicates good method agreement.

In addition, linearity studies showed an average 98.7% recovery when specimens were 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



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Dr. Frederick Jerome
729 West 16th Street, C-4
Costa Mesa, CA 92627

JUL - 3 1997

Re: K971835
Trade Name: Anti-thyroglobulin (Tg) Microplate ELISA
Regulatory Class: II
Product Code: DDC
Dated: May 14, 1997
Received: May 19, 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.

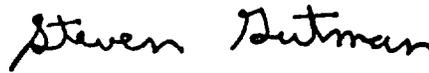
Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

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 at (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>"

Sincerely yours,



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): K971835

Device Name: Anti-thyroglobulin(Tg) Microplate ELISA

The quantitative determination of thyroglobulin autoantibodies in human serum or plasma by a microplate enzymeimmunoassay. Measurements of Tg autoantibodies may aid in the diagnosis of certain thyroid diseases such as Hashimoto, Graves, and nontoxic goiter.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

*Deborah Moore for
Dr. Peter Makin*

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K971835

Prescription Use

OR

Over-The-Counter Use

(Per 21 CFR 801.109)

(Optional Folmat 1-2-96)