

SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness is being submitted in accordance with the requirements of The Safe Medical Devices Act of 1990 (SMDA 1990) and 21 CFR 807.92.

I. GENERAL INFORMATION

Date of Summary Preparation: October 15, 1999

Distributor: BRAHMS Diagnostica, LLC
29 South Peachtree Street
Norcross, Georgia 30092

Manufacturer: BRAHMS Diagnostica GmbH
Komturstrasse 19-20
12099 Berlin, Germany

Contact Person: H. Lee Herron
Partner
BRAHMS Diagnostica, LLC
29 South Peachtree Street
Norcross, Georgia 30092
Tel: 770-449-7738
Fax: 770-449-7739

Device Name: DYNOfest® anti-TPO_n

Common or Usual Name: Radioimmunoassay kit for the determination of anti-thyroid peroxidase antibodies

Classification:

Name:	Thyroid autoantibody immunological test system
Class	Class II
CFR:	21 CFR 866.5870

Substantial Equivalence To: Orgentec Anti-TPO ELISA

II. INTENDED USE

DYNOfest anti-TPO_n is a competitive radioimmunoassay for the quantitative determination of autoantibodies to thyroid peroxidase (TPO) in human serum using the coated tube technique. The DYNOfest anti-TPO_n kit is used as an aid in the diagnosis of Hashimoto's thyroiditis and Graves' disease, autoimmune diseases affecting the thyroid gland.

III. DEVICE DESCRIPTION

DYNOtest anti-TPO_n is a competitive radioimmunoassay intended for the quantitative determination of autoantibodies against thyroid peroxidase in human sera using a coated tube technique. Monoclonal antibodies against thyroid peroxidase bound to the solid phase compete with autoimmune anti-thyroid peroxidase antibodies in the sample for indirectly ¹²⁵I labeled thyroid peroxidase. Following incubation, unreacted indirectly labeled thyroid peroxidase and unreacted ¹²⁵I labeled antibody against TPO is washed from the tube and radioactivity bound to the tube is counted. The measured radioactivity is inversely proportional to the quantity of anti-thyroid peroxidase antibody in the sample.

IV. COMPARISON TO PREDICATE DEVICE

The DYNOtest® anti-TPO_n immunoassay kit is similar to the Orgentec Anti-TPO ELISA (K952129) in the indications for use, performance characteristics and results. The DYNOtest anti-TPO_n test differs from the Orgentec Anti-TPO ELISA in assay format, solid phase and signal. In the DYNOtest anti-TPO_n assay, monoclonal antibodies against thyroid peroxidase bound to the coated tube compete for radioactively labeled thyroid peroxidase with anti-thyroid peroxidase antibodies in the patient samples. The Orgentec Anti-TPO assay uses purified human thyroid peroxidase adhered to the microplate solid phase to capture anti-thyroid peroxidase antibodies in patient samples. Detection of the anti-TPO antibodies in the Orgentec assay is accomplished by incubation with horseradish peroxidase labeled anti-human IgG antibody followed by incubation with enzyme substrate and determination of optical density at 450 nm.

Substantial equivalence to the Orgentec Anti-TPO ELISA kit cleared under K952129 is based on a clinical comparison using 77 serum samples from patients with Graves' disease, Hashimoto's thyroiditis and non-autoimmune thyroid disease. Overall agreement based on a 2 X 2 agreement table was 63/77 = 81.8%.

		Orgentec Anti-TPO ELISA	
		Positive	Negative
DYNOtest Anti-TPO	Positive	58	7
	Negative	7	5

% Agreement = 81.8%

This correlation study demonstrates that the DYNOtest anti-TPO_n assay is substantially equivalent to the legally marketed predicate device, Orgentec Anti-TPO ELISA assay.



DEPARTMENT OF HEALTH & HUMAN SERVICES

NOV 12 1999

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. H. Lee Herron
Partner, BRAHMS, LLC
BRAHMS Diagnostica, LLC
29 South Peachtree Street
Norcross, Georgia 30092

Re: K992791
Trade Name: DYNObest® anti-TPO_n
Regulatory Class: II
Product Code: JZO
Dated: August 18, 1999
Received: August 19, 1999

Dear Mr. Herron:

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 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). 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.

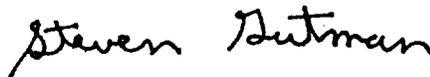
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style with a large initial 'S' and 'G'.

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

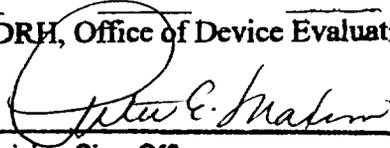
510(k) Number (if known): K992791
Device Name: DYNOfest anti-TPO_n

Indications For Use:

DYNOfest anti-TPO_n is a competitive radioimmunoassay for the quantitative determination of autoantibodies to thyroid peroxidase (TPO) in human serum using the coated tube technique. The DYNOfest anti-TPO_n kit is used as an aid in the diagnosis of Hashimoto's thyroiditis and Graves' disease, autoimmune diseases affecting the thyroid gland.

(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 Clinical Laboratory Devices
510(k) Number K992791

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use