

AUG 6 1998

K981263

SECTION 3
Toxogen - 510(k) SUMMARY
(Summary of Safety and Effectiveness)

Submitted by:

Carol Marble
Senior Regulatory Affairs Specialist
Instrumentation Laboratory Company
113 Hartwell Avenue
Lexington, MA 02173
Phone: (781) 861-4467
Fax: (781) 861-4464

Contact Person:

Carol Marble
Phone: (781) 861-4467

Summary Prepared:

April 6, 1997

Name of the device:

Toxogen

Classification name(s):

866.3780 Toxoplasma gondii serological reagents Class II

Identification of predicate device(s):

K913467/D Toxogen

Description of the device/intended use(s):

Toxogen is an *in vitro* diagnostic, rapid latex particle agglutination test for the qualitative and semiquantitative determination of total anti-toxoplasma antibodies in human serum. The test may be used with a single specimen to estimate the immunologic response of the individual or with paired acute and convalescent sera as an aid in the diagnosis of primary, acute or reactivated toxoplasmosis. This assay is not FDA cleared for use in blood or plasma donor screening.

Statement of how the Technological Characteristics of the Device compare to the Predicate device:

The new Toxogen is a modified version of the predicate Toxogen with a larger latex particle size to increase sensitivity from 10 IU/mL to 5 IU/mL. It is substantially equivalent in performance, intended use, safety and effectiveness to the predicate device as supported by the performance data and labeling.

Summary of Performance Data:

In a method comparison study evaluating 100 serum samples using the qualitative method, the relative sensitivity of the modified Toxogen as compared to the predicate Toxogen was 100% and the relative specificity was 91%.

In a reproducibility study, a panel of 9 serum samples (3 negative, 3 weak positive and 3 high positive) was tested by three different operators on 3 consecutive days following the semiquantitative procedure for Toxogen. The results, as defined by the ability to give agreement to within one 2-fold dilution on the replicates indicated 100% reproducibility.



AUG 6 1998

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Carol Marble
Senior Regulatory Affairs Specialist
Instrument Laboratory
101 Hartwell Avenue
Lexington, MA 02173-3190

Re: K981263
Trade Name: Toxogen
Regulatory Class: II
Product Code: GMM
Dated: June 10, 1998
Received: June 11, 1998

Dear Ms. Marble:

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 (Pre-market 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.

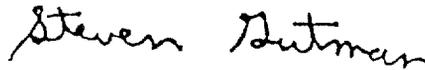
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

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 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): K98 1263

Device Name: Toxogen

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This assay is not FDA cleared for use in blood or plasma donor screening.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Woody Dubois

(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number K981263

Prescription Use X
(Per 21 CFR 801.019)

OR Over-The-Counter Use _____