Product Performance and Substantial Equivalency

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K020237 MAR 1 9 2002

Submitter: Consolidated Technologies
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Contact: Candice Betz

Preparation date: January 21, 2002

Product name (trade & common):
Proprietary: IMMUNOASSAY PLUS CONTROL, Levels 1, 2 and 3
Common: Ligand Plus, Level 1,2, and 3

Also sold as: MAS Immunoassay (IAC) Control, Levels 1,2, and 3
ICN Immunology 1,2

Classification name:
Class I Product code: JJY

21 CFR 862:1660: Multi-Analyte Controls, All Kinds (Assayed and Unassayed)

Predicate device:
QUALITROL IMMUNOASSAY PLUS CONTROL, Levels 1, 2 and 3 (510K 992939)

Device description:
IMMUNOASSAY PLUS CONTROL is designed to monitor the performance of test procedures that analyze immunochemistries and therapeutic drugs as listed in the package insert.
Human origin components are added to a human serum based matrix.

The product contains 0.1% sodium azide.

IMMUNOASSAY PLUS CONTROL will be offered in three levels of 5.0 mL filled vials.

Intended use:
IMMUNOASSAY PLUS CONTROL is a lyophilized human serum based assayed quality control material intended to monitor the performance of serum immunoassay test procedures that analyze immunochemistries and therapeutic drugs as listed in the package insert.

Labeling: Immunoassay Plus Control is sold labeled and unlabeled.

Product Performance and Substantial Equivalency

510(k) Summary (continued)

Comparative analysis:

The table below provides a summary of the technological characteristics between IMMUNOASSAY PLUS CONTROL and the predicate device.

Device Characteristic	IMMUNOASSAY PLUS CONTROL	QUALITROL IMMUNOASSAY PLUS CONTROL
Intended use	Assayed quality control serum for monitoring performance of serum immunoassay and therapeutic drug test procedures.	Assayed quality control serum for monitoring performance of serum immunoassay and therapeutic drug test procedures.
Matrix	Human Serum	Human Serum
Form	Lyophilized	Lyophilized
Vial	5 mL glass	5 mL glass
Analytes	59 analytes of clinical significance that may be found in serum.	68 analytes of clinical significance that may be found in serum.
Storage	2-8°C	2-8°C
Stability	Until expiration date noted on vial label.	Until expiration date noted on vial label.

Conclusions:

The information provided in the pre-market notification demonstrates that IMMUNOASSAY PLUS CONTROL is substantially equivalent to the predicate device, for which there is FDA clearance. This equivalence was demonstrated through comparison of intended uses and physical properties to a commercially available device. The information supplied in the pre-market notification provides reasonable assurance that IMMUNOASSAY PLUS CONTROL is safe and effective for the stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 1 9 2002

Ms. Candice Betz
Quality Manager
Consolidated Technologies
4401 Freidrich Lane
Building 1, Suite 100
Austin, TX 78477-1832

Re: k020237
Trade/Device Name: Immunoassay Plus Control, Levels 1, 2, and 3
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I reserved
Product Code: JJY
Dated: February 18, 2002
Received: March 13, 2002

Dear Ms. Betz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer 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,

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

510K Number: K020237

Device name:

IMMUNOASSAY PLUS CONTROL, Levels 1, 2 and 3

Indications for use:

IMMUNOASSAY PLUS CONTROL, Levels 1, 2 and 3, is a lyophilized human serum based assayed quality control material intended to monitor the performance of clinical immunoassay test procedures that analyze immunochemistries and theraputic drugs as listed in this package insert.

↘ Prescription USE

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K020237