NOV 1 2 1999

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: K992770

Submitter: SeraCare Technology, Inc. DBA Consolidated Technologies
2170 Woodward Street
Austin, TX 78744-1832
Phone: (512) 445-5100
Fax: (512) 445-5515

Contact: Rusty Sewell

Preparation date: August 13, 1999

Product name (trade & common):
Proprietary: Qualitrol Immunology Control, Levels 1, 2 and 3
Common: Not Applicable

Classification name:
Class I , Product code: JJY
21 CFR 862:1660 : Multi-Analyte Controls, All Kinds (Assayed and Unassayed)

Predicate device:
LIQUICHEK IMMUNOLOGY CONTROL,
BIO-RAD Laboratories
K-945651

Device description:
Qualitrol Immunology Control, is designed to monitor the performance of test procedures that analyze immunoglobulin and other proteins in serum. Human origin components are added to a human serum based matrix. The product contains 0.1% sodium azide. Qualitrol Immunology Control will be offered in three levels of 5.0 mL fill vials.

Intended use:
Qualitrol Immunology Control is a lyophilized human serum based assayed quality control material intended to monitor the performance of serum immunological test procedures that analyze immunoglobulins and other serum proteins.

Labeling: Vial labels see Attachments I
Secondary Container label, see Attachments II
Package Insert, see Attachment III

Product Performance and Substantial Equivalency

510(k) Summary (continued)

Comparative analysis:

The table below provides a summary of the technological characteristics between Qualitrol Immunology Control and the predicate device.

Device Characteristic	Qualitrol Immunology Control	Liquichek™ Immunology Plus Control
Intended use	Assayed quality control serum for monitoring performance of serum immunological test procedures.	Assayed quality control serum for monitoring precision of laboratory testing procedures.
Matrix	Human Serum	Human Serum
Form	Lyophilized	Liquid
Analytes	26 analytes of clinical significance that may be found in serum.	24 analytes
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 Qualitrol Immunology 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 Qualitrol Immunology 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

NOV 1 2 1999

Mr. Rusty Sewell
Product Development Engineer
SeraCare Technology, Inc.
DBA, Consolidated Technologies
2170 Woodward Street
Austin, Texas 78744-1832

Re: K992770
Trade Name: Qualitrol Immunology Control, Level 1, 2 and 3
Regulatory Class: I
Product Code: JJY
Dated: August 13, 1999
Received: August 17, 1999

Dear Mr. Sewell:

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.

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,

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

510(k) Number (if known): K992770

Device Name: _____

_____

Indications For Use:

Device name: Qualitrol Immunology Control, Level 1, 2 and 3
Indications for use:

Qualitrol Immunology Control, Level 1, 2 and 3, is a lyophilized human serum based assayed quality control material intended to monitor the performance of clinical immunological test procedures that analyze immunoglobulins and other serum proteins.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter E. Maxim

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K992770

Prescription Use ✓ OR **Over-The-Counter Use** ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)