OCT - 8 1997

SUMMARY OF SAFETY AND EFFECTIVENESS FOR

Boston Biomedica, Inc.'s

ACCURUN™ 140

Reference No: **Product Name:** ACCURUN™ 140 Rubella IgG Positive Control

Sponsor: Boston Biomedica, Inc.
375 West Street
West Bridgewater, MA 02379

1. Indications for use

ACCURUN™ 140 Rubella IgG Positive Control is a human blood based single analyte run control designed to be used as an independent run control with tests for the detection of IgG antibodies to Rubella virus. This control is not intended as a substitute for controls provided with test kits.

ACCURUN™ 140 control is intended to estimate laboratory testing precision and can be used to detect errors in laboratory testing procedures.

2. Device description

ACCURUN™ 140 Rubella IgG Positive Control is manufactured from human serum or plasma containing IgG antibodies to Rubella, but is nonreactive for antibodies to Human Immunodeficiency Virus Types 1 and 2 (HIV 1 and 2), antibodies to Human T-Lymphotropic Virus Type I (HTLV I) and antibodies to Hepatitis C (HCV). This control contains stabilizers (EDTA, buffering agents) and 0.1% ProClin™ as preservative. The manufacturer recommends that the user observe the Centers for Disease Control (CDC) recommended Universal Precautions for handling ACCURUN™ 140 and all human blood.

This product will be made available to clinical laboratory professionals in public health laboratories and clinical laboratories for use with *in vitro* diagnostic tests for the detection of IgG antibodies to Rubella virus in human serum and plasma.

This control is supplied as 1 x 1 ml vial or 1 x 5 ml vial. ACCURUN™ 140 should be stored at 2-8°C. Once opened, ACCURUN™ 140 should be discarded after 60 days.

3. Existing products and practices

Controls of the type represented by Boston Biomedica's ACCURUN™ 140 Rubella IgG Positive Control are relatively new in serology testing for infectious disease markers, but have been in routine use for years with clinical laboratory tests in chemistry and other immunoassay areas. ACCURUN™ 140 is substantially equivalent to other commercially available unassayed, single analyte and multi-analyte independent run controls.

4. Summary of studies

BBI performed five types of stability studies to support the labeling and storage conditions for ACCURUN™ 140 Rubella IgG Positive Control. These include real time, ambient temperature, heat stress, freeze-thaw and open vial stability studies.

In addition, clinical laboratory evaluations were performed at BBI and at two clinical laboratories. The data provided by these external laboratories were collected to evaluate the consistency and performance of ACCURUN™ 140 as an independent run control in situations where it is most likely to be used.

5. Conclusions drawn from studies

We have performed extensive testing to determine the stability of ACCURUN™ 140 Rubella IgG Positive Control under various environmental and user conditions. The data suggest that ACCURUN™ 140 can be stored at 2-8°C in its vialed form and is not affected by multiple freeze-thaw cycles. ACCURUN™ 140 is stable at ambient temperatures and under heat stress for a short period of time with no adverse effects. ACCURUN™ 140 remains stable even after the vials have been repeatedly opened and stored at 2-8°C for at least 60 days.

The clinical trial data demonstrate that ACCURUN™ 140 is safe and effective in three different laboratories with three manufactured ACCURUN™ 140 lots, and under various conditions of stress.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT - 8 1997

Patricia E. Garrett, Ph.D.
Senior Vice President
Strategic Programs and Regulatory Affairs
Boston Biomedica, Inc.
375 West Street
W. Bridgewater, MA 02379

Re: K972986
Trade Name: ACCURUN™ 140 Rubella IgG Positive Control
Regulatory Class: I
Product Code: MJX
Dated: August 8, 1997
Received: August 11, 1997

Dear Dr. Garrett:

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 current Good Manufacturing Practice requirement, 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 at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/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):_____

Device Name: ACCURUN™ 140 Rubella IgG Positive Control

Indications For Use:

Boston Biomedica intends to manufacture and market ACCURUN™ 140 Rubella IgG Positive Control, which is a human blood based single analyte run control designed to be used as an independent run control with tests for the detection of IgG antibodies to Rubella virus. This control is not intended as a substitute for controls provided with test kits.

This product will be made available to clinical laboratory professionals in public health laboratories and clinical laboratories for use with *in vitro* diagnostic tests for the detection of IgG antibodies to Rubella virus in human serum and plasma.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K972986

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

(Optional Format 1-2-96)