OCT - 6 1997

REAADS MEDICAL PRODUCTS, INC.

# SUMMARY OF 510(K) SAFETY AND EFFECTIVENESS

## REAADS Protein C Antigen Test Kit

June 20, 1997

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 REAADS Protein C Antigen Test Kit is compared to a legally marketed predicate device and a substantial equivalence claim is made. The predicate device is the Helena Protein C Antigen Rocket EID Method, currently manufactured and marketed by Helena Laboratories, Beaumont, Texas.

The REAADS Protein C Antigen Test Kit is a sandwich enzyme linked immunosorbent assay (ELISA). The capture antibody specific for human Protein C is coated to 96 microwell polystyrene plate. Diluted patient plasma is incubated in the wells, allowing any available Protein C to bind to the anti-human Protein C antibody bound to the plastic. The plates are washed to remove any unbound Protein C or other plasma molecules. Bound Protein C is quantitated using an HRP conjugated anti-human Protein C detection antibody. Any unbound conjugated anti-human Protein C is washed away after an incubation period. A chromogenic substrate of tetramethylbenzidine (TMB) and hydrogen peroxide ($H_2O_2$) is added to develop a colored reaction. The intensity of the color is measured spectrophotometrically at 450nm in optical density (O.D.) units. Protein C Antigen relative percent concentrations in patient plasma is determined against a curve made from a reference plasma.

The intended use of the device is to quantitatively determine Protein C levels (relative to percent of normal concentration) in human plasma. Normal levels of Protein C are generally accepted to be between 65-150% as compared to a standard or pooled normal plasma. A decreased Protein C activity in plasma may be the result of low concentrations and function (type I) or only low function (type II). The laboratory diagnosis of Protein C deficiency may require both quantitative and qualitiative (functional) determinations.

Test results for clinical samples demonstrate that the performance of the REAADS Protein C Antigen Test Kit and the Helena Protein C Antigen Rocket EID Method is substantially equivalent. The coefficient of correlation (r) for the entire population is 0.949, with a P-value of 0.838 (by single factor ANOVA), indicating the results by the two methods are statistically similar. Although a few minor differences in value recovery were observed between the assays, in general the performance was comparable. The differences may be attributed to the improved specificity of REAADS ELISA technology when compared to EID.

Nanci Dexter — 06/20/97

Nanci Dexter
Director, Quality and Regulatory Affairs

Date

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Nanci Dexter
Director, Quality and
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REAADS MEDICAL PRODUCTS, INC.
12061 Tejon Street
Westminster, Colorado 80234

OCT - 6 1997

Re: K972342
Trade Name: REAADS Protein C Antigen Test Kit
Regulatory Class: II
Product Code: GGP
Dated: July 30, 1997
Received: August 1, 1997

Dear Ms. Dexter:

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

## Indications for Use Statement

**510(k) Number:** K972342

**Device Name:** REAADS Protein C Antigen Test Kit

**Indications for Use:**

The REAADS Protein C Antigen Test Kit is an in vitro diagnostic assay for the quantitative determination of plasma levels of human Protein C (as a percent of normal concentration) by enzyme linked immunosorbent assay (ELISA). Plasma levels of Protein C may be used in conjunction with other assays as an aid in diagnosing congenital or acquired Protein C deficiencies associated with thrombotic disease.

The REAADS Protein C Antigen Test Kit is intended to be used by clinical (hospital and reference) laboratories.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter E. Martin

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K972342

Prescription Use