

SUMMARY OF 510(K) SAFETY AND EFFECTIVENESS

REAADS von Willebrand Factor Antigen Test Kit

July 30, 1997

AUG 13 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 von Willebrand Factor Antigen (vWF:Ag) Test Kit is compared to a legally marketed predicate device and a substantial equivalence claim is made. The predicate device is the Helena Von Willebrand Factor Antigen Rocket EIA (former name: Helena Factor VIII-Related Antigen Rocket EID System) currently manufactured and marketed by Helena Laboratories, Beaumont, Texas.

The REAADS von Willebrand Factor Antigen Test Kit is a sandwich enzyme linked immunosorbent assay (ELISA). The capture antibody specific for human vWF is immobilized to 96-microwell polystyrene plates. Diluted patient plasma is incubated in the wells, allowing any available vWF:Ag to bind to the anti-human vWF antibody bound to the plastic. The plates are rinsed to remove any unbound plasma vWF:Ag molecules. Bound vWF:Ag is quantitated using an HRP conjugated anti-human vWF detection antibody. Any unbound conjugated anti-human vWF is washed away after an incubation period. A chromogenic substrate of tetramethylbenzidine (TMB) and hydrogen peroxide (H₂O₂) is added to develop a colored reaction. The intensity of the color is measured spectrophotometrically at 450nm in optical density (O.D.) units. vWF:Ag relative percent concentrations of patient plasma is determined against a curve made from a reference plasma provided.

The intended use of the device is to quantitatively determine vWF:Ag in citrated human plasma. Normal levels of vWF:Ag are generally accepted to be between 50-160% as compared to a standard or pooled normal plasma. Patients suffering from von Willebrand Disease can have either quantitative levels or decreased function of vWF between 0 - 50% as compared to a standard or pooled normal plasma. The quantitative results from REAADS vWF ELISA may be used in conjunction with functional assay determinations to establish a diagnosis of vWF.

Test results for clinical samples demonstrate that the performance of the REAADS vWF:Ag Test Kit and the Helena Von Willebrand Factor Antigen Rocket EIA Method is substantially equivalent. The coefficient of correlation for the entire population is 0.962, with a P-value of 0.739 (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 EIA.


Nanci Dexter
Director, Quality and Regulatory Affairs

7-30-97
Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Nanci Dexter
Director
Quality and Regulatory Affairs
REAADS Medical Products, Inc.
12061 Tejon Street
Westminster, CO 80234

AUG 13 1997

Re: K972005/S1
REAADS® von Willebrand Factor 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.

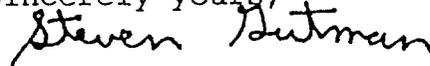
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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 (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: _____

Device Name: REAADS von Willebrand Factor Antigen Test Kit

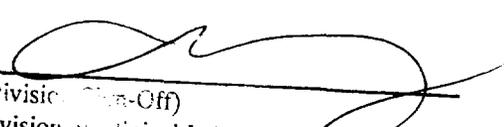
Indications for Use: _____

The REAADS von Willebrand Factor Antigen (vWF:Ag) Test kit is an in vitro diagnostic assay for the quantitative determination of human plasma levels of vWF:Ag (as a percent of normal concentration) by enzyme linked immunosorbent assay (ELISA). Plasma levels of vWF:Ag may be used as an aid in diagnosing von Willebrand disease.

The REAADS vWF:Ag 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)



(Division Chief-Off)
Division of Clinical Laboratory Devices

510(k) Number K072005

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