K993332

FEB 16 2000

GRADIPLASMA LA HIGH AND LOW
PREMARKET NOTIFICATION 510(K) SUMMARY
(Summary of Safety and Effectiveness)

Submitter: Rhonda Pilgrim
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Contact Person: Rhonda Pilgrim
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Date Prepared: January 17, 2000

Trade Name: GradiPlasma LA High and Low

Common or Usual Name: Lupus Anticoagulant Quality Control Plasmas

Classification Name: Control, Plasma, Abnormal
Per 21CFR section 864.7925, Class II

Equivalent Device: Verify® LA Control, K961370

Description of the device / intended use:

GradiPlasma LA High and Low are preparations of fresh human citrated plasma with added buffers and stabilizers, for *in vitro* diagnostic use. The controls are prepared from patients diagnosed with Lupus Anticoagulant and lyophilized in two levels (High and Low) and two volumes (0.5ml and 1.0ml).

GradiPlasma LA High is a high positive control plasma for use in Lupus Anticoagulant clotting test assays, specifically LA SCREEN (DRVVT) and LA CONFIRM (DRVVT) from Gradipore.
GradiPlasma LA Low is a low positive control plasma for use in Lupus Anticoagulant clotting test assays, specifically LA SCREEN (DRVVT) and LA CONFIRM (DRVVT) from Gradipore.

Validation studies for the GradiPlasma LA High and GradiPlasma LA Low have been performed using IL ACL300, IL MLA 800 and Dade Behring BCT instruments.

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Statement of how the technological characteristics of the Device compare to the predicate device

GradiPlasma LA High and Low were compared against Organon Teknika's Verify® LA Control, a 510(k) cleared device. Both devices are unassayed *in vitro* diagnostic controls prepared by lyophilization of known positive lupus anticoagulant patients, with added buffers and stabilizers. Both controls are intended for use in dilute Russell's Viper Venom Time test systems such as LA SCREEN (DRVVT) with phospholipid neutralization tests such as LA CONFIRM (DRVVT). The Verify® LA Control is a single level control whereas the GradiPlasma LA has both a high and low level. Each level of GradiPlasma LA is available in 10 X 0.5ml and 10 X 1.0ml volumes while the Verify® LA Control is available only in 10 X 0.5ml.

Summary of Performance Data

In a comparative performance study on an IL MLA800 instrument, the GradiPlasma LA High and GradiPlasma LA Low exhibited similar within-run variance to the predicate device, Verify® LA Control. Within-run %CV for both levels of GradiPlasma was well below specifications (5%). GradiPlasma LA High gave 1.7% CV with LA SCREEN and 1.4% with LA CONFIRM; GradiPlasma LA Low gave 0.8% with LA SCREEN and 0.9% with LA CONFIRM, while the predicate Verify® LA Control gave 0.8% with LA SCREEN and 2.3% with LA CONFIRM.

In a study comparing reconstituted stability of the devices using a Dade Behring BCT analyzer the GradiPlasma LA High and Low were stable for 8 hours at 2-8°C and were able to be freeze thawed once. The Verify® LA was also stable for 8 hours at 2-8°C.

Conclusion

Based on the data provided, Gradipore concludes that GradiPlasma LA High and Low are substantially equivalent to the predicate device, Verify® LA Control in overall performance characteristics, intended use, safety and effectiveness. The one new performance characteristic of the GradiPlasma LA, (two levels of control), is designed to provide a more comprehensive set of controls for lupus anticoagulant testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

FEB 16 2000

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Rhonda Pilgrim
Regulatory Affairs Manager
Gradipore Limited
Lot 16 Riverside Corporate Park
35-105 Delhi Road, North Ryde 2113
AUSTRALIA

Re: K993332
Trade Name: GradiPlasma LA High and Low
Regulatory Class: II
Product Code: GGC
Dated: January 17, 2000
Received: January 19, 2000

Dear Ms. Pilgrim:

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.

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 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

INTENDED USE STATEMENT

510(k) Number (If known): 993332

Device Names: GradiPlasma LA-High and GradiPlasma LA - Low

Indications For Use:

GradiPlasma LA High is a high positive control plasma for use in Lupus Anticoagulant clotting test assays, specifically LA SCREEN (DRVVT) and LA CONFIRM (DRVVT) from Gradipore.

GradiPlasma LA Low is a low positive control plasma for use in Lupus Anticoagulant clotting test assays, specifically LA SCREEN (DRVVT) and LA CONFIRM (DRVVT) from Gradipore.

Validation studies for the GradiPlasma LA High and GradiPlasma LA Low have been performed using IL ACL300, IL MLA 800 and Dade Behring BCT instruments.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter E. Maxim

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K993332

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

(Optional Format 1-2-96)

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