K061803



**11) 510K Summary**

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:_____

**a) Applicant Name and Address**

| | |
|---|---|
| Applicant: | Diagnostica Stago, Inc. |
| Address: | 5 Century Drive<br>Parsippany, NJ 07054 |
| Contact Person: | Melissa Cole |
| Phone #: | 800-222-2624, x 4416 |
| Fax #: | 973-631-1618 |
| E-mail: | Melissa.Cole@stago-us.com |
| Date of Preparation: | June 22, 2006 |

**b) Device Name**

| | |
|---|---|
| Trade Name: | STA® - Control LA 1+2 |
| Common Name: | Lupus Control Plasmas |
| Classification Name: | Plasma, Control, Normal & Abnormal |

**c) Predicate Device**

Cryocheck Lupus Positive Control (K952623) manufactured by Precision Biologic, Inc. Dartmouth, Nova Scotia, Canada.

**d) Intended Use/Device Description**

The STA® – Control LA 1+2 kit provides a lupus anticoagulant (LA) negative plasma and a LA positive plasma. These plasmas are intended for the quality control of LA testing using the following kits:

STA® – Staclot® dRVV Screen (#00339 & 00333)
STA® – Staclot® dRVV Confirm (#00334)
Staclot® LA (#00600, 00594)

**e) Technological Characteristic Summary**

STA® – Control LA 1+2 and Cryocheck Lupus Positive Control are human citrated plasmas intended for control of Lupus Anticoagulant testing (i.e. DRVVT and Staclot LA).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Laura A. Worfolk, Ph.D.
Acting Director, Quality Control
and Regulatory Affairs
Diagnostica Stago, Inc.
Five Century Drive
Parsippany, New Jersey 07054

JUL 28 2006

Re: k061803
Trade/Device Name: STA®- Control LA 1+2
Regulation Number: 21 CFR § 864.5425
Regulation Name: Plasma, Control, Normal & Abnormal
Regulatory Class: II
Product Code: GGC, GGN
Dated: June 23, 2006
Received: June 27, 2006

Dear Dr. Worfolk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Robert L. Becker, Jr., MD, Ph.D
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

**510(k) Number (if known):** _____

**Device Name:** STA® - Control LA 1+2

**Indications for Use:**

The STA® - Control LA 1+2 kit provides a lupus anticoagulant (LA) negative plasma and a LA positive plasma. These plasmas are intended for the quality control of the tests for LA detection carried out with the following tests:

STA® –Staclot® dRVV Screen (#00339 & #00333)
STA® –Staclot® dRVV Confirm (#00334)
Staclot® LA (#00600, 00594)

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

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Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K061803