MAY 14 2002

EXHIBIT #1

510(K) 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: K020823

1. **Submitter's Identification:**

Sanquin Blood Supply Foundation (formerly the Central Laboratory of the Netherlands Red Cross Blood Transfusion Service)
Plesmanlaan 125
1066 CX Amsterdam
The Netherlands

Date Summary Prepared: March 4, 2002

2. **Name of the Device:**

Peliclass™ Human IgG Subclass Nephelometric IMMAGE® Kit

3. **Predicate Device Information:**

Peliclass™ Human IgG Subclass Nephelometric Array® Kit, K#982023, Inova Diagnostics, Inc.

4. **Device Description:**

Sheep antibodies to human IgG subclasses will react with the four subclasses of human IgG immunoglobulins, forming immuno-precipitates. This reaction consequently causes changes in the intensity of scattered light at a rate that increases gradually at first, then rapidly and finally proceeds through a peak rate of change (peak rate value) for the component being analyzed.

5. **Intended Use:**

The contents of the Peliclass™ Human IgG Subclass Nephelometric IMMAGE® Kit will allow quantitative determination of all four IgG Subclasses in at least 50 serum samples with the Beckman IMMAGE® Immunochemistry System. The determination of IgG subclasses is to be used in conjunction with other clinical findings to aid in the assessment of the humoral immune status.

We trust that the aforementioned responses will be satisfactory.

We will mail, under separate cover, a complete copy of the contents of this fax to Document Mail Center.

If you have any questions, or require additional information, please feel free to call me at (480) 451-7502 or FAX me at (516) 482-0186

Sincerely,

Sanquin Blood Supply Foundation (Formerly the Central Laboratory of the Netherlands Red Cross Blood Transfusion Service)

Susan D. Goldstein-Falk/da

Susan D. Goldstein-Falk
Official Correspondent for
Sanquin Blood Supply Foundation (Formerly the Central Laboratory of the Netherlands Red Cross Blood Transfusion Service)

SDG-F/da

Attachments

A complete list of Attachments is annexed hereto:

Attachment #1: Page 1 of your 510(k) Summary Reflecting the Updated "Indications For Use Form".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Susan D. Goldstein-Falk
Official Correspondent for
Sanquin Blood Supply Foundation
c/o MDI Consultants, Inc.
55 Northern Boulevard, Suite 200
Great Neck, New York 11021

MAY 14 2002

Re: k020823
Trade/Device Name: Peliclass™ Human IgG Subclass Nephelometric IMMAGE® Kit
Regulation Number: 21 CFR § 866.5510
Regulation Name: Immunoglobulins A,G, M, D AND E Immunological Test System
Regulatory Class: II
Product Code: DFZ
Dated: March 12, 2002
Received: March 14, 2002

Dear Ms. Goldstein-Falk:

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 the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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/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

510(k) Number (if known): K020823

Device Name: Peliclass™ Human IgG Subclass Nephelometric IMMAGE® Kit

Indications For Use:

The contents of the Peliclass™ Human IgG Subclass Nephelometric IMMAGE® Kit will allow quantitative determination of all four IgG Subclasses in at least 50 serum samples with the Beckman IMMAGE Immunochemistry System. The determination of IgG subclasses is to be used in conjunction with other clinical findings to aid in the assessment of the humoral immune status.

Susan S. Alta.e

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K020823

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The-Counter Use ____ (Optional Format 1-2-96)