JUN - 7 2000

K992799

SECTION 10: 510 (k) SUMMARY

Name of Contact Person:
John J. Kiang
Business and Product Development Consultant
Former President, Director and CEO and Founder (1996 – November 1998)
Licensed Clinical Chemist Scientist (CA)

Name of Proposed Device: Sangui BioTech, Inc. EPO [Erythropoietin] ELISA

Common name of the device: Erthyropoietin Assay

Classification name: EPO [Erythropoietin] Assay

Name of Predicate Device: Nichols Institute Diagnostics EPO [Erythropoietin] Assay Chemiluminescent Assay (Coated Bead Technology) Catalog Number: 60-4205, to which this firm claims substantial equivalency.

Description of the proposed device: Quantitative determination of EPO [Erythropoietin] in human serum. This immunoassay is based on the principles of the two site "sandwich" Enzyme-Linked ImmunoSorbent Assay (ELISA).

Intended Use of the proposed device: The intended use of this product is the quantitative determination of erythropoietin levels in human serum. This assay is intended as an aid in the diagnosis of anemias and polycythemias. With the advent of the administration of recombinant erythropoietin as a biologic therapy to increase red blood cell mass, an erythropoietin assay may be used also to aid in the prediction and monitoring of response to recombinant erythropoietin treatment in persons with anemias.

Technological characteristics: Similarities:

- The intended use.
- Both kits are based on the 2-site immunometric (sandwich) assay principles.
- The anitbodies used, which consists of a carboxyl-terminal mouse monoclonal antibody and an affinity purified region-restricted amino-terminal sheep antibody.
- Solid phase, both are coated with avidin.
- Capture Antibodies are coupled with biotin.

Technological characteristics: Differences:

- Sensitivity – the analytical proposed device is 2.0 mU/mL vs. 0.7 mU/mL for the predicate device. The limitation of the proposed device in sensitivity has been documented in the labeling of the proposed device, i.e. Paragraph 4, Page 7 of the Package Insert, following the Guidance Document of the FDA.
- Incubation or reaction time for the immunoassay.
- Standard range for the Sangui kit and the predicate device (Nichols Institute Diagnostics)
- Sample size.
- Tag antibody: horseradish peroxidase labeled vs. acridinium ester labeled.
- Solid Phase – microwell vs. bead.
- Suggested normal ranges.

Based on the study on one hundred twenty-six (126) patient sera analyzed using both the proposed device and the predicate device, a correlation coefficient (R) of 0.96 was obtained with a slope of 0.88 and an intercept of –1.63. The samples studied ranged from 5 to 291 mU/mL of EPO [Erythropoietin] in the Nichols Institute Diagnostics' kit. The data clearly demonstrates excellent correlation between the two devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN - 7 2000

Mr. John J. Kiang
Business and Product Development Consultant
Sangui Biotech, Inc.
1508 Brookhollow Drive
Santa Ana, California 92705

Re: K992799
Trade Name: Sangui BioTech, Inc. EPO [Erythropoietin] ELISA Kit
Regulatory Class: III
Product Code: GGT
Dated: November 11, 1999
Received: November 15, 1999

Dear Mr. Kiang:

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

Section 6c: **Statement of Indications for Use**

510 (k) Number: K992799

Device Name:
Sangui BioTech, Inc. EPO [Erythropoietin] ELISA Kit

Indications For Use:
The intended use of this product is the quantitative determination of erythropoietin levels in human serum. This assay is intended as an aid in the diagnosis of anemias and polycythemias. With the advent of the administration of recombinant erythropoietin as a biologic therapy to increase red blood cell mass, an erythropoietin assay may be used also to aid in the prediction and monitoring of response to recombinant erythropoietin treatment in persons with anemias.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter E Maheux

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K992799

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

(Optional Format 1-2-96)