AUG 1 9 1998

K982608

Sangui BioTech, Inc .

1508 Brookhollow Drive, Suite 354
Santa Ana, California 92705 USA
714-429-7807 (Voice)
714-429-7808 (Fax)

SECTION 10: 510 (k) SUMMARY

Name of Contact Person: *John J. Kiang*

Name of Proposed Device: Sangui BioTech, Inc. ACTH [Adrenocorticotropic Hormone] ELISA

Common name of the device: *in vitro* Diagnostic Kit

Classification name: Radioimmunoassay, ACTH

Name of Predicate Device: Nichols Institute Diagnostics ACTH [Adrenocorticotropic Hormone] Radioisotopic Assay Catalog Number: 40-2194 or 40-2195, to which this firm claims substantial equivalency.

Description of the proposed device: Quantitative determination of ACTH in human EDTA plasma. 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 ACTH in human EDTA plasma.

Technological characteristics: Similarities:

- The intended use
- Both kits are based on immunometric (sandwich) assay principles.
- Sample size and type.
- The antibodies used, which consist of a mouse monoclonal antibody and a goat polyclonal antibody.
- Suggested normal range for the Sangui kit and the predicate device (Nichols Institute Diagnostics).
- Solid phase, both are coated with avidin [microwell vs. bead]
- Capture antibodies are coupled with biotin.

Technological characteristics: Differences:

- Sensitivity – the analytical proposed device is 0.5 vs. 1 pg/mL for the predicate device
- Incubation or reaction time for the immunoassay.
- Standard range for the Sangui kit and the predicate device (Nichols Institute Diagnostics)
- Tag antibody: enzyme labeled vs. radiolabeled
- Tag antibody: 1-24 epitope vs. 1-17 epitope.

Based on the study on one hundred seventeen (117) patient plasma analyzed using both the proposed device and the predicate device, a correlation coefficient (R) of 0.995 was obtained with a slope of 0.976 and an intercept of 4.2. The samples studied ranged from 1.5 to 1,045 pg/mL of ACTH in the Nichols Institute Diagnostics' kit. The data clearly demonstrates excellent correlation between the two devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 19 1998

John J. Kiang, M.S.
President and CEO
Sangui BioTech, Inc.
1508 Brookhollow Drive, Suite 354
Santa Ana, California 92705

Re: K982608
ACTH (Adrenocorticotropic Hormone) ELISA Kit
Regulatory Class: II
Product Code: CKG
Dated: July 24, 1998
Received: July 27, 1998

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 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.

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 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: K982608

Device Name:
Sangui BioTech, Inc. ACTH [Adrenocorticotropic Hormone] ELISA Kit

Indications For Use:
The intended use of this product is the quantitative determination of ACTH [Adrenocorticotropic Hormone] in human EDTA plasma. This immunoassay is based on the principles of the two site "sandwich" Enzyme-Linked ImmunoSorbent Assay (ELISA).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K982608

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

(Optional Format 1-2-96)