Sangui BioTech, Inc .

1508 Brookhollow Drive, Suite 354
Santa Ana, California 92705 USA
714-429-7807 (Voice)
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DEC 23 1997

SECTION 9: 510 (k) SUMMARY

Name of Contact Person: *John J. Kiang or* Patrick Onishi.

Name of Proposed Device: Sangui BioTech, Inc. INTACT-PTH [Parathyroid Hormone] ELISA

Common name of the device: Intact PTH (Parathyroid hormone) *in vitro* Diagnostic Kit

Classification name: Radioimmunoassay, Parathyroid hormone

Name of Predicate Device: Nichols Institute Diagnostics *Allégro*® Intact PTH (Parathyroid Hormone) kit, to which this firm claims substantial equivalency.

Description of the proposed device: Quantitative determination of Intact Parathyroid Hormone (PTH) 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 Intact Parathyroid Hormone (PTH) in human serum.

Technological characteristics: Similarities:
- the intended use
- The antibodies used, which are all polycolonal antibodies from goats and are all purified via affinity chromatography.
- Both kits are based on immunometric (sandwich) assay principles.
- Analytical sensitivity.

Technological characteristics: Differences:
- Sample size
- Incubation or reaction time for the immunoassay.
- Tag [enzyme label antibody vs. radiolabeled antibody].
- Solid Phase.

Based on the study on one hundred and twenty-three (123) patient sera analyzed using both the proposed device and the predicate device, a correlation coefficient (R) of 0.99 was obtained with a slope of 0.997 and an intercept of 2.9. The samples studied ranged from 3.2 to 805 pg/mL of intact PTH in the Nichols' kit. The data clearly demonstrates excellent correlation between the two devices. Further, another predicate device, the *ACTIVE* ™ I-PTH ELISA kit, currently manufactured by Diagnostic Systems Laboratories, Inc. (DSL), Webster, Texas 77598-4217, uses the same principle, ELISA, as this proposed device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 23 1997

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

Re: K974306
INTACT-PTH [Parathyroid Hormone] ELISA Diagnostic Kit
Regulatory Class: II
Product Code: CEW
Dated: November 13, 1997
Received: November 31, 1997

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: K974306

Device Name:
Sangui BioTech, Inc. INTACT-PTH (Parathyroid Hormone) ELISA

Indications For Use:
The intended use of this product is the quantitative determination of Intact Parathyroid Hormone (PTH) in human serum. This immunoassay is based on the principles of the two site "sandwich" Enzyme-Linked ImmunoSorbent Assay (ELISA). The measurement of parathyroid hormone levels in the disease states is intended for the differential diagnosis of hypercalcemia and hypocalcemia resulting from the disorders of calcium metabolism.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K974306

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)