K052617

FEB 2 3 2006

510(k) SUMMARY

Safety and Effectiveness

"This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 866.5340"

Ferritin LIT Assay / Ferritin Calibrator Set / Ferritin Control-L, Control-H

Submitter

Name,	Good Biotech Corp.
Address,	38 34th Road, Taichung Industrial Park Taichung 407 Taiwan
Telephone number,	+886-4-23596873
Contact person,	Victor Chiou
Preparation date	September 20, 2005

Device

Trade name,	Ferritin LIT Assay
	Ferritin Calibrator Set
	Ferritin Controls, Level-L & Level-H
Common name,	Ferritin immunological diagnostic assay
	Ferritin calibrator
	Ferritin control
Classification name	Ferritin immunological test system (21 CFR § 866.5340)
	Calibrator (21 CFR § 862.1150)
	Quality control material (assayed and unassayed) (21 CFR § 862.1660)

Predicate Device

Trade name,	Biokit quantex Ferritin
	Biokit quantex FERRITIN standard multipoint
	Biokit quantex FERRITIN / MYOGLOBIN / IgE control I/II
510(k) number	K040879

Description

Good Biotech Corp. Ferritin LIT Assay is a ready to use reagent for the quantitative determination of ferritin by latex particle enhanced immunoturbidimetry (LIT). Duck anti-ferritin IgY(ΔFc) is coupled to polystyrene microparticles, which greatly increase the analytical sensitivity. When ferritin of the sample encounters with the latex microparticles sensitized with duck anti-ferritin IgY(ΔFc), agglutination among the latex microparticles occurs based on the antigen-antibody reaction. The agglutination increases the turbidity of the sample and the degree of agglutination is detected by the absorbance change at 570 nm. The value of the absorbance change is proportional to the ferritin concentration of the sample and is recorded by a general chemistry autoanalyzer. Then, the actual ferritin concentration of the sample is determined by interpolation of the calibration curve obtained by standard samples with known ferritin concentrations.

Intended Use

Reagent:
Good Biotech Corp. (GBC) Ferritin LIT Assay is intended to be used for the quantitative determination of ferritin in human serum by latex particle enhanced immunoturbidimetry (LIT). Measurement of ferritin aids in the diagnosis of diseases affecting iron metabolism.

Calibrator:
GBC Ferritin Calibrator Set is intended to be used with GBC Ferritin LIT Assay for the quantitative determination of ferritin in serum samples.

Control:
GBC ferritin Controls are intended to be used as the assayed quality control material for ferritin analysis.

For In Vitro Diagnostic Use.

For Prescription Use Only

Substantial Equivalence

Comparative performance studies conducted on 50 serum samples yielded high correlation coefficient upon comparison of the GBC Ferritin LIT system and the predicate devices, Biokit quantex Ferritin. The result is summarized below:

Comparative Method	Slope	Intercept (ng/ml)	Correlation Coefficient	n
Biokit quantex Ferritin	1.07	-17.73	0.9808	50

Conclusion

Good Biotech Corp. Ferritin LIT assay, calibrator set and controls are substantially equivalent to the predicate devices based on their intended purposes, design and the comparison performance results.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 2 3 2006

Good Biotech Corp.
c/o Mr Victor Chiou
President
38, 34th Rd
Taichung Industrial Park
Taichung, TW 407.

Re: k052617
Trade/Device Name: Ferritin LIT Assay, Ferritin Calibrator Set and Ferritin Controls, Level L and Level H
Regulation Number: 21 CFR 866.5340
Regulation Name: Ferritin immunological test system
Regulatory Class: Class II
Product Code: DBF, JIT, JJX
Dated: September 20, 2005
Received: September 23, 2005

Dear Mr. Chiou:

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 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 advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance 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., M.D., Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K 052617

Device Name: Ferritin LIT Assay
Ferritin Calibrator Set
Ferritin Controls, Level-L & Control-H

Indications For Use:

Good Biotech Corp. (GBC) Ferritin LIT Assay system is intended to be used for the quantitative determination of ferritin in human **serum** by latex particle enhanced immunoturbidimetry (LIT). Measurement of ferritin aids in the diagnosis of diseases affecting iron metabolism.

GBC Ferritin Calibrator Set is intended to be used with GBC Ferritin LIT Assay for the quantitative determination of ferritin in serum samples.

GBC Ferritin Controls are intended to be used as the assayed quality control material for ferritin analysis.

For In Vitro Diagnostic Use.

For Prescription Use Only.

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

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Maria Chan
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K052617