K050713

JUN 6 - 2005

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 807.92."

Duet hs-CRP LIT Assay/ Duet hs-CRP Calibrator Set

Submitter

Name,	Good Biotech Corp.
Address,	38 34th Rd. Taichung Industrial Park Taichung 407 Taiwan
Telephone number,	+886-4-23596873
Contact person,	Victor Chiou
Preparation date	March 18, 2005

Device

Trade name,	Duet hs-CRP LIT Assay Duet hs-CRP calibrator set
Common name,	CRP immunological diagnostic assay CRP calibrator
Classification name	C-reactive protein immunological test system (21CFR 866.5270) Calibrator (21CFR 862.1150)

Predicate Device

Trade name,	K-ASSAY CRP (3) K-ASSAY Multi-Calibrator D
510(k) number	K023828

Description

Duet hs-CRP LIT kit is the ready-to-use reagent suitable for quantification of C-reactive protein by latex particle enhanced immunoturbidimetry (LIT). Duck anti-CRP IgY (ΔFc) is

coupled to polystyrene microparticles, which greatly increased the analytical sensitivity. When CRP of the sample encounters with the latex microparticles sensitized with duck anti-CRP 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 CRP concentration of the sample and is recorded by a general chemistry autoanalyzer. Then, the actual CRP concentration of the sample is determined by interpolation of the calibration curve obtained by standard samples with known CRP concentrations.

Intended Use	Good Biotech Corp. Duet hs-CRP LIT Assay is intended to be used as a high sensitive assay for the quantitative determination of C-reactive protein in serum by latex particle enhanced immunoturbidimetry (LIT). Highly sensitive measurement of C-reactive protein is useful for the detection and evaluation of infection, tissue injury, inflammatory disorders and associated diseases. Good Biotech Corp. Duet hs-CRP Calibrator Set is intended to be used with Duet hs-CRP LIT Assay for the quantitative determination of C-reactive protein in serum samples. For *in vitro* diagnostic use.
Special Instrument Requirements	Duet hs-CRP LIT kit is a "ready to use" reagent kit for clinical chemistry auto-analyzers. Duet hs-CRP LIT kit has been tested on the Hitachi 911 Clinical Chemistry analyzer.
Substantial Equivalence	Duet hs-CRP LIT kit was compared with Kamiya Biomedical Company's K-ASSAY CRP (3) to demonstrate the substantial equivalence. Testing was performed on the Roche Diagnostics Hitachi 911 analyzer.

Item	Device	Predicate
Reagent		
Name	Duet hs-CRP LIT Assay	K-ASSAY CRP (3)
Intended Use	Good Biotech Corp. Duet hs-CRP LIT Assay is intended to be used as a high sensitive assay for the quantitative determination of C-reactive protein in serum by latex particle enhanced immunoturbidimetry (LIT). Highly sensitive measurement of C-reactive protein is useful for the detection and evaluation of infection, tissue injury, inflammatory disorders and associated diseases.	The K-ASSAY CRP (3) is intended to be used as a high-sensitive assay for the quantitative determination of CRP in serum and plasma by immunoturbidimetric assay. Measurement of C-Reactive Protein aids in the detection and evaluation of tissue injury, inflammatory disorders, and related diseases.
Methodology	Latex particle enhanced immunoturbidimetry	Latex particle enhanced immunoturbidimetry
Test Objective	C-reactive protein	C-reactive protein
Type of Test	Quantitative	Quantitative
Product Type	Reagent 1 (R 1): Reactive buffer solution Reagent 2 (R 2): Latex suspension	Reagent 1 (R 1): Reactive buffer solution Reagent 2 (R 2): Latex suspension
Antibody □Source□	Duck anti-CRP IgY(ΔFc) □Egg Yolk□	Rabbit anti-CRP antibodies □Serum□
Calibration Mode	Spline	Spline
Sample Volume	2 μl/test	3 μl/test
Reagent Volume	R1□150 μl/test R2□150 μl/test	R1□150 μl/test R2□150 μl/test

Wavelength Selection	Main-wavelength:570 nm Sub-wavelength: 800 nm	Main-wavelength:570 nm Sub-wavelength: 800 nm
Assay Range	0.3-200 mg/L	0.1-320 mg/L (standard protocol)
Interference	Bilirubin C: up to 45 mg/dl Bilirubin F: up to 45 mg/dl Hemoglobin: up to 805-mg/dl hemoglobin Lipemia: up to 10 g/L Liposyn® (fat emulsion)	Bilirubin C: up to 30 mg/dl Bilirubin F: up to 30 mg/dl Hemoglobin: up to 500 mg/dl Lipid: up to 3000 mg/dl Interfat
Calibrator		
Name	Duet hs-CRP Calibrator Set	K-ASSAY Multi-Calibrator D
Target Analyte	C-reactive protein	C-reactive protein
Matrix	Human serum	Human serum
Traceability	Traceable to IFCC CRM470	Traceable to IFCC CRM470
Preservative	Sodium Azide	Sodium Azide
Preparation	Liquid (ready-to-use)	Liquid (ready-to-use)

Correlation

$y = 0.955\ x + 0.938$ mg/L
x = K-ASSAY CRP (3)
y = Duet hs-CRP LIT Assay
$R^2 = 0.998$
N = 93 (CRP conc.: 0~ 200 mg/L)

$y = 1.075\ x + 0.226$ mg/L
x = K-ASSAY CRP (3)
y = Duet hs-CRP LIT Assay
$R^2 = 0.996$
N = 64 (CRP conc.: 0~ 10 mg/L)

Conclusion

Good Biotech Corp. Duet hs-CRP LIT assay and calibrator set 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

JUN 6 - 2005

Mr. Victor Chiou
President
Good Biotech Corp.
38 34th Road Taichung Industrial Park
Taichung City, 407 Taiwan

Re: k050713
Trade/Device Name: Duet hs-CRP LIT Assay
Duet hs-CRP Calibrator Set
Regulation Number: 21 CFR 866.5270
Regulation Name: C-reactive protein immunological test system
Regulatory Class: Class II
Product Code: DCN, JIT
Dated: May 10, 2005
Received: May 11, 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 Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety 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,

Carol C. Benson

Carol C. Benson, M.A.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050713

Device Name: Duet hs-CRP LIT Assay ; Duet hs-CRP Calibrator Set

Indications For Use:

Good Biotech Corp. Duet hs-CRP LIT Assay is intended to be used as a high sensitive assay for the quantitative determination of C-reactive protein in serum by latex particle enhanced immunoturbidimetry (LIT). Highly sensitive measurement of C-reactive protein is useful for the detection and evaluation of infection, tissue injury, inflammatory disorders and associated diseases.

Good Biotech Corp. Duet hs-CRP Calibrator Set is intended to be used with Duet hs-CRP LIT Assay for the quantitative determination of C-reactive protein in serum samples.

For In Vitro Diagnostic Use.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 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)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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