

5. 510(k) Summary

Summary of Safety and Effectiveness Information Supporting a Substantially Equivalent Determination

Device description

The Gentian cystatin C immunoassay is a particle enhanced turbidimetric immunoassay (PETIA). The immunoparticles are made from activated polystyrene microspheres to which avian anti-human cystatin C antibodies are covalently attached. The immunoparticles and cystatin C form aggregations that change the absorbance signal, depending on the amount of cystatin C present. Measurements obtained by this device are used for the determination of Cystatin C in human serum and plasma. The Gentian cystatin C assay is calibrated with human Cystatin C calibrators. Cystatin C controls are assayed for the verification of the accuracy and precision of the Gentian cystatin C immunoassay.

Substantial Equivalence

The Gentian Cystatin C immunoassay is substantially equivalent to the Dade Behring, Inc., N Latex Cystatin C Test Kit (K003503) with respect to indications for use, device design and material. The basic difference between the new device and the Dade Behring predicate device is in assay technology and the instruments used for testing. The Gentian assay is a particle enhanced turbidimetric immunoassay (PETIA), while the Dade Behring assay is a particle enhanced immunonephelometric assay (PENIA). The Gentian device can be used on all commercially available automated clinical chemistry analyzers using a light absorption detection system, while the Dade Behring test is applicable only on the Dade Behring, Inc. Nephelometer Systems. In the Gentian device avian antibodies are used and it is known by one skilled in the art that there is no interaction between Rheumatoid Factor (RF) and avian antibodies. The Dade Behring predicate device use antibodies with the inherent possibility for a false reactions with Rheumatoid Factor (RF).

Comparison to predicate device

The substantial equivalence, safety and efficacy of the Gentian cystatin C immunoassay to Dade Behring N Latex Cystatin C assay (K003503) was evaluated in two studies and on two different automated clinical chemistry analyzers. In total 4 study sites were involved. The issues addressed in these studies were the comparison between Gentian cystatin C immunoassay and the predicate device Dade Behring N Latex Cystatin C assay (K003503) (Table 1). In addition external validation performance of the new device was evaluated at two study sites (Table 2).

Table 1. Summary of method comparison regression analysis

	Instrument application	Slope (95% CI)	Intercept (95% CI)	R	Cystatin C range (mg/L)	N
Study 1	Modular P vs. BNII	1.075	0.009	0.986	0.53 - 9.47	172
	Modular P vs. BN ProSpec	1.048	0.059	0.992	0.53 - 9.47	174
Study 2	Modular P vs. BN ProSpec	1.021	-0.025	1.00	0.61 - 6.44	76
	Architect vs. BN ProSpec	0.975	-0.059	0.989	0.51 - 7.95	87

Table 2. External validation performance data

Sample	Mean cystatin C (mg/L)	Within run CV (%)	Between day CV (%)	Between site CV (%)	Between lot CV (%)	Total precision CV (%)	Recovery (%)
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L	0.82	2.4	3.54	0.86	0.55	4.41	103.8
M	1.77	1.49	2.36	0.84	0.54	2.78	107.3
H	3.94	1.38	1.23	0.0	0.64	1.95	107.7

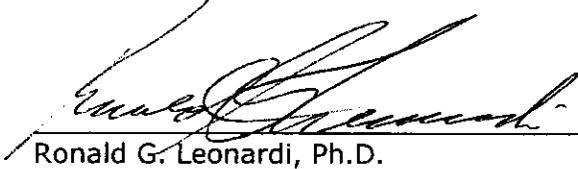
Performance characteristics

The measuring range is 0.3-8.0 mg/L. The reference range is 0.52-0.98 mg/L. Total analysis time is 10 minutes. Linearity is demonstrated over the whole assay range, the Gentian Cystatin C immunoassay is linear in the range 0.34 - 8.4 mg/L on Modular P and in the range 0.27 - 8.8 mg/L on Architect. Total imprecision CV, measured over 20 days with two lots, is 4.2%. Interference studies with drugs and anticoagulants show no significant interference, also there is no significant interference from hemoglobin (8 g/L), intralipid (11 g/L), tricyclerides (14 g/L) and bilirubin (420 mg/L). Due to the use of avian antibodies, no interference with rheumatoid factor is detected. No carry-over is detected. The limit of detection (LoD) and limit of quantification (LoQ) (within CV 6%) are both within given acceptance criteria and below the lowest calibrator concentration. Sample stability is up to one month at 2-8°C. Stability of the reagents at 2-8°C is calculated to be at least 18 months. Stability of the reagents in use is minimum 4 weeks. Recovery is 99-110 %. Antigen hook effect was observed in samples with spiked cystatin C concentrations above 16 mg/L, this will have no significant impact on patient serum and plasma samples, since sample concentrations above 9 mg/l never have been reported. Serum and plasma evaluations give identical cystatin C results. Between instrument comparison regression analysis shows excellent agreement between Gentian Cystatin C when measured on Architect ci8200 and Modular P instruments.

Conclusion

When considering the comparison studies between Gentian cystatin C immunoassay and the Dade Behring, Inc., N Latex Cystatin C Test Kit (K003503) and the additional documentation supporting the Gentian cystatin C immunoassay, it can be concluded that the Gentian cystatin C immunoassay when measured on Architect ci8200 and Modular P analyzers is as safe and effective as, and substantially equivalent to the Dade Behring, Inc., N Latex Cystatin C assay.

Submitted by:

 Oct. 5, 2007
 Ronald G. Leonardi, Ph.D. Date

President
 R & R REGISTRATIONS
 P.O. Box 262069, San Diego, CA 92196



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Gentian AS
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President of R & R Registrations
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NOV - 6 2007

Re: k071388
Trade/Device Name: Gentian Cystatin C Immunoassay
Regulation Number: 21 CFR §862.1225
Regulation Name: Creatinine test system
Regulatory Class: Class II
Product Code: NDY
Dated: October 05, 2007
Received: October 09, 2007

Dear Dr. Leonardi:

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).

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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) 276-0490. 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 (240) 276-3150 or at its Internet address at <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Jean M. Cooper, M.S., D.V.M.

Director

Division of Chemistry and Toxicology

Office of *In Vitro* Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K071388

Device Name: Gentian Cystatin C immunoassay

Indication For Use:

Gentian Cystatin C Immunoassay is an *in-vitro* diagnostic test for quantitative determination of cystatin c in human serum and plasma. The measurement of cystatin c is used in the diagnosis and treatment of renal diseases.

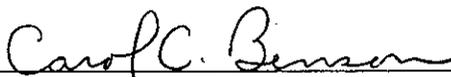
Prescription Use X
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use
(21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)


Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K071388