OCT 2 5 2005

510(k) Summary

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Date of Preparation of this Summary:	May, 28 2005
Device Trade or Proprietary Name:	Sentinel Clin Chem Cal
Device Common/Usual Name or Classification Name:	Calibrator
Classification Number/Class:	JIX/Class II

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.

The assigned 510(k) number is: K051452

Test Description:

The Sentinel Sentinel Clin Chem Cal is a device intended for medical purposes for use in pancreatic amylase and cholinesterase assays to establish points of reference that are used in the determination of values in the measurement of pancreatic amylase and cholinesterase in human serum and plasma.

Intended Use:

Sentinel Clin Chem Cal must be used only for the calibration of clinical chemistry tests.

Description of the Calibrator Material:

Sentinel Clin Chem Cal contains the analytes in human serum matrix. The analytes consist of pancreatic amylase and cholinesterase.

Assigned Values and Value Assignment Process:

Four vials of calibrator are reconstituted by weight (acceptability 2.970-3.030 g) following the Instruction for Use.
To evaluate vial variability, Pancreatic Amylase is assayed in three replicates on each vial and %CV is calculated for each vial. If %CV is equal to or greater than 4.5%, the vial is discarded from the analysis. At least 2 vials of calibrator can be used. If more than 3 vials are discarded, another set of four calibrator must be used.

The pool of all accepted vials is aliquoted in small volumes and stored at -20 °C.

The Pancreatic Amylase and Cholinesterase assay are calibrated against the previous calibrator lot, stored at 2-8 °C and freshly reconstituted. During each testing run, two levels (normal and abnormal) of control materials are assayed to ensure the effectiveness of the measurements.

For three consecutive days (three runs), three replicates of Pancreatic Amylase and Cholinesterase are assayed on Hitachi 717. The average of all replicates is calculated (X1).
Pancreatic Amylase and Cholinesterase are also assayed on Abbott ARCHITECT® *c*8000®. Five vials of freshly reconstituted by weight vials are assayed in five replicates on *c*8000. The average of all replicates is calculated (X2).

The assigned value (Xm) is the mean of the two average: Xm=(X1+X2)/2

Directions for Use:

Refer to Draft Calibrator Labeling on page 17

Performance Characteristics:

1. **Precision/Reproducibility**

   N/A

2. **Linearity/assay reportable range**

   N/A

3. **Traceability (controls, calibrators, or method)**

   The Sentinel Clin Chem Cal is traceable to the following referenced standards:

	Analyte	Method	Standardization
AmyP	Pancreatic Amylase	IFCC EPS / 37 °C	ε p-Nitrophenol
ChE	Cholinesterase	DGKC Butyrylthiocholine 37 °C	ε Hexacyano-ferrate (III)

4. **Detection limit (functional sensitivity)**

   N/A

5. **Analytical specificity**

   N/A

6. **Assay cut-off**

   N/A

7. **Calibrator Shelf-life Stability**

   The calibrator shelf-life stability was determined by the recovery method on one lots of Sentinel Clin Chem Cal. One lot of test calibrator were stored at 4°C. At the time of analysis was reconstituted with distilled water. Percent recovery was calculated for each calibrator level by dividing the result of the test calibrator at

time zero by the result of control calibrators at every testing point. At each testing point, fresh reagent, control calibrators, and test calibrators were analyzed. Calibrators were tested at multiple test points through a minimum of 30 months. Target recovery was 95% to 105% for the test calibrators as compared to the Time zero. Results are found in Table 1.

The results show the calibrators are stable for up to 33 months. The resulting claim is 24 months from date of manufacture.

Since the calibrator is purchased from Roche which is the Predicate Device for the Sentinel Clin Chem Cal, Shelf life of the calibrator is the same as the Predicate Device.

8. Calibrator After Reconstitution Stability

After Reconstitution stability was assessed on three lots of calibrator: one expired from 13 months (expiry date + 13 months), one expired from 8 months (expiry date + 8 months) and one still in validity.
The calibrator after reconstitution stability was determined by the recovery method. Percent recovery was calculated for each calibrator analyte by dividing the results of the reconstituted vial stored at 2 – 8 °C after 2 days, and at -20 °C after 14 days by the results of a freshly reconstituted vial of the same lot. At each test point fresh reagents were used.
Acceptance criteria is 100 ± 7%.

Results are found in Table 2 and Table 3.

Stability of reconstituted material: 2 days at 2 to 8 °C or 14 days at -20 °C if aliquoted in small volumes.

Table 1
Sentinel Sentinel Clin Chem Cal
Real Time Stability – Pancreatic Amylase and Cholinesterase

Time	Cholinesterase (U/L)	P - Amylase (U/L)
0 Monhts	4581	148.8
1 Mo	4618	150.6
% Rec	**100.8**	**101.2**
4 Mo	4627	151.3
% Rec	**101.0**	**101.7**
8 Mo	4590	152.4
% Rec	**100.2**	**102.4**
11 Mo	4636	150.6
% Rec	**101.2**	**101.2**
14 Mo	4503	144.6
% Rec	**98.3**	**97.2**
17 Mo	4595	151.0
% Rec	**100.3**	**101.5**
20 Mo	4485	151.5
% Rec	**97.9**	**101.8**
23 Mo	4508	147.2
% Rec	**98.4**	**98.9**
26 Mo	4576	150.0
% Rec	**99.9**	**100.8**
29 Mo	4663	154.2
% Rec	**101.8**	**103.6**
33 Mo	4636	148.7
% Rec	**101.2**	**99.9**

Table 2
Sentinel Sentinel Clin Chem Cal
After Reconstitution Stability – Pancreatic Amylase

STABILITY AFTER RECOSTITUTION — SENTINEL

product: Clin chem Cal — **ref 16550** — **at 2-8°C and - 20°C**

Used Material

Instrument.	HITACHI 717				
reagent lot	**Pancreatic amylase**	**17631**	lot	**31147**	exp : mar/2005
	Clin Chem Cal	**REF 16550**	lot	**P0690**	exp : jun/2006
	Clin Chem Cal	**REF 16550**	lot	**3 differents lots**	

Acceptability criteria

Calibration/Check system: 1) The D% (factor and controls) between days must be less 5%
2) all replicates of controls must be in the target range

Stability after recostitution Calibrator: 1) The % Recovery (%R) between days must range 93-107%

Calibration /Check system (reagents+ instruments)

sample	supplier	lot	Expired date	time of valutation	expected value	replicates	time 0 value	2 days (2-8°C) value	2 days (2-8°C) D % (2d vs To)	14 days (-20°C) value	14 days (-20°C) D % (30d vs To)
blank						Dabs	0.0005	0.0002		0.0000	
calibrator	**Sentinel**	**P0690**	**jun / 2006**	2 months after manufacturing	**151**	Dabs	0.0473	0.0449		0.0455	
						factor	3226	3378	4.7%	3319	2.9%
Precinorm U	Roche	apr/2004	still valid	12 months after manufactoring	39 ±7	1	42	40		43	
						2	39	39		37	
						3	37	41		38	
Precipath U	roche	feb/2004	still valid	14 months after manufacturing	102 ± 18	1	108	103		107	
						2	106	107		102	
						3	105	105		109	
mean	control		Precinorm U	Roche	apr/2004		39.3	40.0	1.7%	39.3	0.0%
			Precipath U	roche	feb/2004		106.3	105.0	-1.3%	106.0	-0.3%

The factor and controls meet the criteria of acceptability — P YES * NO

3 lots calibrator stability after recostitution

sample	supplier	lot	Expired date	time of valutation	expected value	replicates	time 0 value	2 days (2-8°C) value	2 days (2-8°C) %R (2d vs To)	14 days (-20°C) value	14 days (-20°C) %R (30d vs To)
Clin Chem Cal	Sentinel	M0750	sep/2002	**13 months expired**	183 target NA	1	191	197		204	
						2	184	201		198	
						3	199	194		194	
		M0796	jan/2003	8 months expired	172 target NA	1	180	185		183	
						2	173	187		188	
						3	186	178		185	
		P0690	jun/2006	still valid	151 target NA	1	153	155		154	
						2	150	155		157	
						3	153	150		153	
Mean	calibrator		Clin Chem Cal	Sentinel	M0750		191.3	197.3	103%	198.7	104%
					M0796		179.7	183.3	102%	185.3	103%
					P0690		152.0	153.3	101%	154.7	102%

Conclusion The calibrator meet the acceptability criteria and the stability after recostitution is :
2 days at 2-8°C or 14 days at -20°C

QC (date Signature) 02/10/2003

Ezio Marelli
Technical Manager
SENTINEL CH.

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Table 3
Sentinel Sentinel Clin Chem Cal
After Reconstitution Stability – Cholinesterase

STABILITY AFTER RECOSTITUTION — SENTINEL

product: Clin chem Cal — **ref 16550** — **at 2-8°C and - 20°C**

Used Material

Instrument.	HITACHI 717				
reagent lot	**Cholinesterase liquid**	**REF 17019A**	lot	**30863**	exp : Oct/ 2004
	Clin Chem Cal	**REF 16550**	lot	**P0690**	exp : jul/ 2006
	Clin Chem Cal	**REF 16550**	lot	**3 differents lots**	

Acceptability criteria

Calibration/Check system: 1) The D% (factor and controls) between days must be less 5%
2) all replicates of controls must be in the target range

Stability after recostitution Calibrator: 1) The % Recovery (%R) between days must range 93-107%

Calibration /Check system (reagents+ instruments)							time 0	2 days (2-8°C)		14 days (-20°C)	
sample	supplier	lot	Expired date	time of valutation	expected value	replicates	value	value	D % (2d vs To)	value	D % (30d vs To)
blank						Dabs	-0.0036	-0.0029		-0.0031	
calibrator	Sentinel	P0690	jun / 2006	2 months after manufacturing	5920	Dabs	0.0399	-0.0396		-0.0407	
						factor	-87774	-86817	-1.1%	-84724	-3.5%
Precinorm U	Roche	apr/2004	still valid	12 months after manufactoring	6700 ± 1100	1	6721	6641		6638	
						2	6641	6701		6703	
						3	6734	6851		6890	
Precipath U	roche	feb/2004	still valid	14 months after manufacturing	6300 ± 1000	1	6278	6286		6245	
						2	6273	6340		6269	
						3	6185	6204		6265	
mean	control		Precinorm U	Roche	apr/2004		6698.7	6731.0	0.5%	6743.7	0.7%
			Precipath U	roche	feb/2004		6245.3	6276.7	0.5%	6259.7	0.2%

The factor and controls meet the criteria of acceptability — P YES * NO

3 lots calibrator stability after recostitution							time 0	2 days (2-8°C)		14 days (-20°C)	
sample	supplier	lot	Expired date	time of valutation	expected value	replicates	value	value	D % (2d vs To)	value	D % (30d vs To)
Clin Chem Cal	Sentinel	M0750	sep/2002	**13 months expired**	4850 target NA	1	4677	4677		4868	
						2	4785	4785		4754	
						3	4891	4891		4661	
		M0796	jan/2003	8 months expired	5010 target NA	1	5001	5001		5101	
						2	5014	5014		5007	
						3	5104	5104		4980	
		P0690	jun/2006	still valid	5920 target NA	1	5821	5821		5904	
						2	5811	5811		5801	
						3	5945	5945		5901	
Mean	calibrator		Clin Chem Cal	Sentinel	M0750		4784.3	4784.3	100%	4761.0	100%
					M0796		5039.7	5039.7	100%	5029.3	100%
					P0690		5859.0	5859.0	100%	5868.7	100%

Conclusion The calibrator meet the acceptability criteria and the stability after recostitution is :
2 days at 2-8°C or 14 days at -20°C

QC (date Signature) 02/10/2003

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 25 2005

Mr. Davide Spada
Application Specialist
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Re: k051452
Trade/Device Name: Sentinel Clinical Chemistry Calibrator
Regulation Number: 21 CFR 862.1150
Regulation Name: Multi-Analyte Calibrator
Regulatory Class: Class II
Product Code: JIX
Dated: August 5, 2005
Received: August 19, 2005

Dear Mr. Spada:

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,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K051452

Device Name: Sentinel Clin Chem Cal

Indications For Use:

Clinical Chemistry – The Sentinel Clin Chem Cal is a device intended for medical purposes for use in pancreatic amylase and cholinesterase assays to establish points of reference that are used in the determination of values in the measurement of pancreatic amylase and cholinesterase in human serum and plasma.

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

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

K051452