510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION

DECISION SUMMARY

A. 510(k) Number:
K092330

B. Purpose for Submission:
New device.

C. Measurand:
Human hemoglobin in feces

D. Type of Test:
Qualitative, Automated Immunoassay

E. Applicant:
Polymedco Inc**.**

F. Proprietary and Established Names:
OC-Sensor DIANA iFOB Test

G. Regulatory Information:

1. Regulation section: 21 CFR 864.6550, Occult blood test.
2. Classification: Class II
3. Product code: OOX, Automated Occult Blood Analyzer
4. Panel: Hematology

H. Intended Use:

1. Intended use(s):
   "OC-Sensor DIANA iFOB Test" is designed to be used together as an immunoassay test system. The test system is intended for the qualitative detection of fecal occult blood in feces by professional laboratories.
2. Indication(s) for use:
   The automated test is used for the determination of gastrointestinal (GI) bleeding, found in a number of gastrointestinal disorders (GI), e.g. colitis, polyps, and colorectal cancer. The OC-Sensor DIANA iFOB Test is recommended for use in:
   1. Routine physical examinations
   2. Monitoring bleeding in patients
   3. Screening for colorectal cancer or gastrointestinal bleeding
3. Special conditions for use statement(s):
   For prescription use only
4. Special instrument requirements:
   OC-Sensor DIANA iFOB Test

I. Device Description:

The device is comprised of the following system components:

a) Test reagents (latex, buffer, wash concentrate, calibrator, negative and positive controls, sample collection bottles)
b) collection devices
c) analyzer

The work flow of the device is as follows:

a) The samples are collected in the sample collection bottles that are sent home with the patient.
b) The sample collection bottles are returned to the laboratory.

c) The inverted sample collection bottles are racked and placed onto the instrument platform on the rack.
d) The samples are analyzed as the racks move through the analyzer.
e) The sample collection bottle is punctured and a sample is pipet into the cuvette followed by the latex reagent and mixed.
f) Analysis flow: Dispense sample; Dispense latex/buffer; Mix; Measure; Wash cells (wash solution); Wash cells (purified water); Wash cells (purified water); Wash cells (absorption of purified water).
g) Measurements are taken between the mixing cycles. After a series of washes the blank is read and the final results are calculated (human hemoglobin concentrations in ng/ml) and printed.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   OC Auto Micro FOB Test
2. Predicate 510(k) number(s):
   K041408
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended use / indications for use	Automated quantitative detection of fecal occult blood in feces by professional laboratories.	Same
Device design	Test system components: Test reagents (latex, buffer, wash concentrate, calibrator, negative and positive controls, sample collection bottles) and collection devices; analyzer.	Same
Principle of operation	Measurement of hemoglobin antibody-antigen reaction by latex turbidimetry.	Same
Work flow	Samples are taken by the patient and analyzed within a laboratory	Same
Prozone effect	> 12,000 ng/mL hemoglobin in buffer	Not reported
Specificity	Limitation statement in package insert	Comparable
Quality control reagents	OC Auto Micro iFOB Controls	Same

Differences		
Item	Device	Predicate
Through-put	280 samples / hour	80 samples / hour

K. Standard/Guidance Document Referenced (if applicable):

- "Screening Checklist for Traditional/Abbreviated Premarket Notification [510(k)] Submissions", rev.5/30/07;
- "Third Party Premarket Notification Checklist for Acceptance (Part II)";
- FDA guidance "Review Criteria for Assessment of Qualitative Fecal Occult Blood In Vitro Diagnostic Devices": 2007;
- „Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices": 2005;

- "Guidance for the Off-The-Shelf Software Use in Medical Devices": 1999

List of relevant standards:

- IEC 61010-1;
- IEC 61010-2-010;
- IEC 61010-2-101;
- IEC 61326-1;
- IEC 61326-2-6;
- ISO 14971;
- ISO 62304;
- ISO 17511;
- CLSI EP5-A2;
- CLSI EP6-A
- CLSI EP17-A

L. Test Principle:

The principle of measurement employed for the reagent system is latex agglutination. The test reagent contains an immunoassay utilizing polyclonal antibodies attached to a polystyrene latex particle.

This test principle is well established and the same as utilized by the predicate comparison device.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

The intra assay precision was assessed using three levels of control samples at 50 ng/mL, 135 ng/mL and 880 ng/mL hemoglobin in buffer. All the replicates of the 50 ng/mL were negative and all the replicates of the 135 ng/mL and 880 ng/mL samples were positive. The inter assay precision was assessed using three levels of control samples at 50 ng/mL, 155 ng/mL and 615 ng/mL hemoglobin in buffer and tested once per day over 20 days. All the replicates of the 50 ng/mL were negative and all the replicates of the 155 ng/mL and 615 ng/mL were positive.

b. Assay reportable range:

Assay reportable range not applicable. Results >100 ng/mL reported as positive and results 100 ng/mL or lower reported as negative.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

Not applicable.

d. Detection limit:

Not applicable.

e. Analytical specificity:

The package insert contains a statement in the limitations section regarding Hb variants (the test has not been validated for testing of patients with hemoglobinopathies).

Note: The consumables (reagent kits, calibrator, and quality controls) used for the new device are identical to the ones used for the predicate device ("OC Auto Micro FOB Test").

f. Assay cut-off:

The cut-off is 100 ng/mL of hemoglobin in buffer.

2. Comparison studies:

a. Method comparison with predicate device:

Correlation studies with the comparative method (predicate device "OC Auto Micro 80

iFOB Test") were conducted at two sites in the USA. Samples submitted for routine analysis were consecutively measured on the new device and on the predicate device at each site. At one hospital site, 971 consecutive samples were analyzed. At the other hospital site, 6584 consecutive samples were analyzed. Positive Percent Agreement (PPA), Negative Percent Agreement (NPA) and Overall Percent Agreement were determined. The results are summarized below:

Site 1 Long Island City, NY — n = 967 — CI

	OC Micro		
OC Diana	Positive	Negative	
Positive	80	4	98.77% PPA — 93.34%-99.78%
Negative	1	882	99.55% NPA — 98.85%-99.83%
Total	81	886	

99.48% OPA — 98.79%-99.78%

Site 2 Concord, CA — n = 6584 — CI

	OC Micro		
OC Diana	Positive	Negative	
Positive	632	21	98.90% PPA — 97.75%-99.47%
Negative	7	5924	99.65% NPA — 99.46%-99.77%
Total	639	5945	

99.57% OPA — 99.38%-99.70%

Combined Sites 1 and 2 NY + CA — n = 7551 — CI

	OC Micro		
OC Diana	Positive	Negative	
Positive	712	25	98.89% PPA — 97.82%-99.44%
Negative	8	6806	99.63% NPA — 99.46%-99.75%
Total	720	6831	

99.56% OPA — 99.38%-99.69%

OPA=100% x (a+b)/(a+b+c+d), PPA= 100% x a/(a+c), NPA=100% x d/(b+d)

b. Matrix comparison:
Not applicable.

3. Clinical studies:
a. Clinical Sensitivity:
Not applicable
b. Clinical specificity:
Not applicable
c. Other clinical supportive data (when a. and b. are not applicable):
Not applicable

4. Clinical cut-off:
100 ng/mL hemoglobin in buffer

5. Expected values/Reference range:
Not applicable.

N. Instrument Name: OC-Sensor DIANA iFOB Test.
Note: The name of the test is the same as the instrument.

O. System Descriptions:

1. Modes of Operation: Batch, Stat, Closed tube, Automatic
2. Software:
   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:
   Yes ___x_____ or No _____
3. Specimen Identification: Manual sample identification by fill in of required information on the sample bottle, including a manual load list or a barcode.
4. Specimen Sampling and Handling:
   The work flow is as follows:

a) The samples are collected in the sample collection bottles that are sent home with the patient.
b) The sample collection bottles are returned to the laboratory.
c) The inverted sample collection bottles are racked and placed onto the instrument platform on the rack.
d) The samples are analyzed as the racks move through the analyzer.
e) The sample collection bottle is punctured and a sample is pipet into the cuvette followed by the latex reagent and mixed.
f) Analysis flow: Dispense sample; Dispense latex/buffer; Mix; Measure; Wash cells (wash solution); Wash cells (purified water); Wash cells (purified water); Wash cells (absorption of purified water).
g) Measurements are taken between the mixing cycles. After a series of washes the blank is read and the final results are calculated (human hemoglobin concentrations in ng/ml) and printed.

5. Calibration:
   With OC Sensor DIANA, latex turbidimetry is used to measure the amount of an antigen or an antibody by measuring changes in the scattered light rays in latex agglutination. The absorbance of the reaction mixture increases in proportion to the concentration of hemoglobin in the specimen.
   A calibration curve is created by dilution of a primary calibrator that contains a known concentration of hemoglobin. The curve is created by plotting the known concentration against the absorbance values. The concentration of hemoglobin is then determined by reading the unknown absorbance values off of the standard curve. The qualitative test result is indicated.
6. Quality Control:
   The consumables (reagent kits, calibrator, and quality controls) used for the new device are identical as the ones used for the predicate device ("OC Auto Micro FOB Test").
   The negative and positive controls are used to monitor the performance of the analyzer using X-bar control method. The negative control contains 5 mL of buffer and the positive control contains 5 mL of 200 ng/mL purified hemoglobin in buffer.
   The quality controls are identified in the labeling information.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

Not applicable.

Q. Proposed Labeling:

The labeling information of the new device is contained in the submitted 510(k) documentation. The information is comprised of the following documents:

- New device:
  a) OC Sensor DIANA reagents device labeling (comprising: Latex, Buffer, Wash Solution)
  b) OC Sensor DIANA Operator's manual
  c) OC Automated Calibrator Kit labeling, comprising:
    - OC Automated Calibrator Kit carton label
    - OC Automated Calibrator label
    - OC Automated Diluent label
    - OC Automated Calibrator instructions for use

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.