K024182

MAR 0 3 2003

Precision Systems™, Inc ™
ANALETTE /STANBIO Reagents 510 (k)

1. **Submitted by:**

Precision Systems™, Inc.
16 Tech Circle
Natick MA. 01748
Establishment Reg'n No. 1250003
Attention: Bill Haden

2. **Product Name:**

A. Proprietary Name:
Precision Systems™ ANALETTE™ Chemistry Analyzer
STANBIO Laboratorys Reagents

B. Classification Name:
Chemistry analyzer, micro, for clinical use, 75JJF
Common or Usual Name: Chemistry analyzer (Class I)
STANBIO Laboratory Reagents
Calcium Test System (Class II) CJY 21
Creatinine Test System (Class II) CGX 21
Phosphorus Test System (Class I) CEO 21
Albumin Test System (Class II) CIX 21
Total Protein Test System (Class II) CEK 21
Glucose Test System (Class II) CGA 21
Urea Nitrogen Test System (Class II) CDQ 21
Magnesium Test System (Class I) JGJ 21
Creatine Kinase Test System (Class II) CGS 21
Alkaline Phosphatase Test System (Class II) CJE 21
Cholesterol(included HDL) Test System (Class I) CHH 21
Triglycerides Test System (Class I) JGY 21
Total Bilirubin Test System (Class II) CIG 21
Direct Bilirubin Test System (Class II) CIG 21
Uric Acid Test System (Class II) KNK 21
Lactate Dehydrogenase L Test System (Class II) CFJ 21
Alanine Aminotransferase Test System (Class II) CKA 21

Aspartate Aminotransferase Test System (Class II) CIT 21
Gamma Glutamyl Transferase Test System (Class I) JQB 21
Chloride Test System (Class I)

3. **Intended Use:**

The Precision Systems™ ANALETTE™ Chemistry Analyzer is intended for the quantitative determination of Calcium, Creatinine, Phosphorus, Albumin, Total Protein, Glucose, Urea Nitrogen, Magnesium, Creatine Kinase, Alkaline Phosphatase, Cholesterol(includes HDL), Triglycerides, Total Bilirubin, Direct Bilirubin, Uric Acid, Lactate Dehydrogenase L, Alanine Aminotransferase, Aspartate Aminotransferase, Gamma Glutamyl Transferase, Chloride,and etc. analytes in solution such as serum, plasma, or urine. It is an "open" System, which can use a variety of commercially manufactured reagents such as but not limited to Synermeds® Reagents, Medical Analysis Systems Reagents and STANBIO Laboratory Reagents. .

4. **Classification:**

The FDA has classified Microchemistry analyzer for clinical use as Class I as published in the Federal Register of May 1, 1987, section 862.2170. FDA has classified Enzyme analyzer for clinical use as Class I as published in the Federal Register of May 1, 1987, section 862.2500. The FDA has classified Calcium, Creatinine, Albumin, Total Protein, Glucose, Urea Nitrogen, Creatine Kinase, Alkaline Phosphatase, Total Bilirubin, Direct Bilirubin, Lactate Dehydrogenase L, Lactate, Aspartate Aminotransferase test systems into Class II (performance Standards). Gamma Glutamyl Transferase, Phosphorus, Magnesium, Cholesterol(includes HDL), Triglycerides, Uric Acid, Alanine Aminotransferase, and, Chloride test systems into Class I.

5. **Compliance with Section 514**

Performance specifications: None established under Section 514.

6. **Labeling:**

ANALETTE™ Application Sheets: **Exhibit A**
Synermed Chemistry inserts/applications sheets IR 200/ ANALETTE™ and Medical Analysis Systems inserts: **Exhibit B**
STANBIO Laboratory inserts: **Exhibits C**
Distribution of STANBIO Reagents with the Analette will be under STANBIO Laboratory Labeling except with the PSI inserts (application data sheets)

7. **Substantial Equivalence:**

Exhibit D. Precision Systems™ approved 510k K013654 for the ANALETTE™ using Synermed® Reagents and Precision Systems™ approved 510k K022072 for the ANALETTE™ using Medical Analysis Systems Inc® Reagents.
Exhibit E. Acceptance Criteria.
Exhibit F. Acceptance Criteria
Exhibit G. Data

Chemistry Classification and 510k Numbers

Chemistry	Synermed 510 k	Class	STANBIO 510k	Section
Calcium	953395	II	Mkted prior 5/76	862.1145
Creatinine	943924	II	771856	862.1225
Phosphorus	912569	I	800297	862.1580
Albumin	903543	II	771771	862.1035
Total Protein	903511	II	Mkted prior 5/76	862.1635
Glucose	903063	II	832159	862.1345
Urea Nitrogen	911248	II	962418	862.1770
Magnesium	902919	I	883170	862.1495
Creatine Kinase	930932	II	972155	862.1215
Alkaline Phosphatase	931986	II	941313	862.1050
Cholesterol(includes HDL)	903015	I	831863	862.1175
Triglycerides	903016	I	831858	862.1705
Uric Acid	923414	I	831864	862.1775
Lactate Dehydrogenase L	921025	II	Exempt 11/98 (63 FR 59225)	862.1440
Alanine Aminotransferase	921016	II	941314	862.1030
Aspartate Aminotransferase	915555	II	932049	862.1100
Gamma Glutamyl Transferase	931958	I	941315	862.1360
Chloride	903103	I	781635	862.1170
	Medical Analysis 510k			
Total Bilirubin	861413	II	810055	862.1110
Direct Bilirubin	900259	II	810055	862.1110

A. Introduction: The ANALETTE™, 510k Number K013654, is the Synermed® IR 200, 510k Number K971491, and uses the above Synermed® reagents with each of their above 510k numbers. Medical Analysis Systems' reagents have all also been 510k'ed with the noted above 510k numbers. STANBIO Laboratory's reagents have all also been 510k'ed with the noted above 510k

numbers. The use of STANBIO Laboratory's Reagents should also be classified in Class I as has Synermed and MAS reagents on the ANALETTE™.

B. Overview: Precision Systems™ Inc. at 16 Tech Circle, Natick MA, 01760 manufactures The ANALETTE™. It has been commercially available as the IR 200 with Synermed® reagents since April 1997. It has been commercially available as the Analette with Synermed® reagents since June 2002. It has been commercially available as the Analette with Medical Analysis Systems' reagents since August 2002.

C. The Precision Systems™ Inc. ANALETTE™ using STANBIO Laboratory's Reagents should be classified Class I as published in the Federal Register of May 1, 1987, section 862.2170 because for the purpose of the Act, it is substantially equivalent to the Synermed® IR 200/ ANALETTE™ using Synermed and MAS reagents and therefore the Hitachi® 705, both products in commercial distribution.

D. Comparison to the Predicate Product:
EQUIVALENCE:
The Precision Systems™ Inc. ANALETTE™ is identical to the Synermed® IR 200(OEM'ed to Synermed®) product in commercial using Synermed® reagents. The ANALETTE™ is an open system and is intended for use in conjunction with certain materials (Synermed® reagents, Medical Analysis Systems' reagents, STANBIO Laboratory reagents, or etc.) to measure a variety of analytes and enzymes found in human serum, plasma, urine, spinal fluid, etc. All data collection, data reduction, and instrument operation for the ANALETTE™ using Synermed® and MAS reagents are the same as that used for STANBIO Laboratory reagents. Application parameters may vary depending on optimization or manufactures insert suggested parameters.

DIFFERENCES:
The ANALETTE™ is an open system and currently has been FDA approved for use with Synermed® and Medical Analysis reagents. Synermed® reagents, Medical Analysis Systems reagents, and STANBIO Laboratory reagents are approved to be used on open systems. STANBIO Laboratory reagents are not currently approved for use on or distribution with the ANALETTE™.

E. Chemistry Methodologies:
Synermed® and MAS chemistries that have been 510k approved on the Synermed® IR200 and/ or the ANALETTE™. Their methodology is shown in their respective insert Exhibit B. STANBIO Laboratory reagents have been 510k approved for use on an open system. Their methodology is shown in their respective insert Exhibit C

F. Procedures:

Imprecision: Two control serums were used to carry out the determination of within run and total precision of each Synermed® and Medical Analysis Systems reagents and the STANBIO Laboratory Reagents. Each sample was measured in duplicate for up to 20 days for total precision. Similarly, within run precision was determined with up to 20 repeats of two control serums to eliminate reagent preparation variance, control serum drift, and repeated calibrations.

Correlation: Samples were assayed for correlation as part of the Imprecision procedure using each of Synermeds® reagents and Medical Analysis Systems Reagents, and STANBIO Laboratory Reagents A comparison is made between the two Commercial reagents run on the ANALETTE™ using Synermeds® or Medical Analysis Systems reagents as the reference.

Linearity: Commercially available linearity material was assayed and Least Square linear regression was used to determine expected linearity. A comparison is made between STANBIO Laboratory Reagents and the Least Square line to establish the linearity.

Recovery: Commercial available Controls with assigned values for Medical Analysis Systems Reagents were used to determine recovery, which was conducted as part of the imprecision study.

G. Results:

Imprecision: Results in **Table 1** and **Table 2** vs insert values indicate that serum controls give acceptable/equivalent results using the described procedure for within run and total imprecision with each of the representative test methods.

Correlation: Results obtained with about 100 serums using each of the Synermeds® or Medical Analysis Systems Reagents as the reference tests were compared to those with STANBIO Laboratory Reagents. Slopes, Intercepts and Correlation Coefficients show acceptable results. The regression(slope and intercept) and correlation coefficients are shown in **Table 3** and **Graphs 1-21**. Acceptable results are shown between both methods.

Linearity results are shown in **Table 4** vs insert values. Linearity did not exceed the Manufacturers' claim.

Recovery results using assigned control serums ranges are shown in **Table 5.** Acceptable results are shown between both methods.

No modifications have been made in the STANBIO Laboratory Reagents nor packaging; therefore, the Normal Range, Sensitivity, and Stability will remain as recommended by the manufacture. The above data support equivalence; therefore, these parameters were not tested.

H. Conclusions:

For the above reasons, we believe the ANALETTE™ clinical chemistry analyzer using STANBIO Laboratory Reagents to be substantially equivalent to the ANALETTE™ clinical chemistry using Synermeds® or Medical Analysis Systems Reagents.

Should you require further information or have questions, please contact me at: 508 655 7010. Bill Haden

Summary of Safety and Effectiveness: June 14, 2002

Manufacturer:

Precision Systems™, Inc.
16 Tech Circle
Natick, MA. 01760
Attention: Bill Haden

STANBIO Laboratory, Inc
1261 North Main Street
Boerne, Texas 78006-3014

Proprietary Name:

ANALETTE™
STANBIO Laboratory Reagents:
Calcium,
Creatinine
Phosphorus
Albumin
Total Protein
Glucose
Urea Nitrogen
Magnesium
Creatine Kinase
Alkaline Phosphatase
Cholesterol(includes HDL)
Triglycerides
Total Bilirubin
Direct Bilirubin
Uric Acid

	Lactate Dehydrogenase L	
	Alanine Aminotransferase	
	Aspartate Aminotransferase	
	Gamma Glutamyl Transferase	
	Chloride	
Classification Name:	Chemistry analyzer, micro	862.2500
	Calcium	862.1145
	Creatinine	862.1225
	Phosphorus	862.1580
	Albumin	862.1035
	Total Protein	862.1635
	Glucose	862.1345
	Urea Nitrogen	862.1770
	Magnesium	862.1495
	Creatine Kinase	862.1215
	Alkaline Phosphatase	862.1050
	Cholesterol(includes HDL)	862.1175
	Triglycerides	862.1705
	Total Bilirubin	862.1110
	Direct Bilirubin	862.1110
	Uric Acid	862.1775
	Lactate Dehydrogenase L	862.1440
	Alanine Aminotransferase	862.1030
	Aspartate Aminotransferase	862.1100
	Gamma Glutamyl Transferase	862.1360
	Chloride	862.1170

Intended Use:	An in vitro diagnostic automated clinical chemistry analyzer for the analysis of analytes in solution.
Predicate Device:	Precision Systems™, Inc, ANALETTE™ using Synermeds® or Medical Analysis Systems reagents.
Performance:	Substantially equivalence was established in comparative studies. It was concluded from these results that this product is safe and effective.
Safe Medical Device Act 1990	Precision Systems™ will make any additional safety and effectiveness information for the ANALETTE™ Clinical Chemistry Analyzer available to interested persons upon request.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 0 3 2003

Mr. Bill Haden
VP Scientific and Regulatory Affairs
Precision Systems, Inc.
16 Tech Circle
Natick, MA 01760

Re: k024182
Trade/Device Name: Precision Systems Analette Chemistry Analyzer & Stanbio Laboratory Reagents
Regulation Number: 21 CFR 862.1770
Regulation Name: Urea nitrogen test system
Regulatory Class: Class II
Product Code: CDQ; CEO; CGA; CGS; CGX; CHH; CHJ; CIG; CIT; CIX; CJE; CJY; JGJ; JGY; JJF; KNK
Dated: December 19, 2002
Received: December 19, 2002

Dear Mr. Haden:

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 (301) 594-3084. 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/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

PRODUCT: PRECISION SYSTEMS ANALETTE CHEMISTRY ANALYZER & STANBIO Laboratory REAGENTS

INDICATIONS FOR USE STATEMENT

The Precision Systems™ ANALETTE™ Chemistry Analyzer is intended for the quantitative determination of Calcium, Creatinine, Phosphorus, Albumin, Total Protein, Glucose, Urea Nitrogen, Magnesium, Creatine Kinase, Alkaline Phosphatase, Cholesterol(includes HDL), Triglycerides, Total Bilirubin, Direct Bilirubin, Uric Acid, Lactate Dehydrogenase L, Alanine Aminotransferase, Aspartate Aminotransferase, Gamma Glutamyl Transferase, Chloride, and etc. analytes in solution such as serum, plasma, or urine. It is an "open" System, which can use a variety of commercially manufactured reagents such as but not limited to Synermeds® Reagents, Medical Analysis Systems Reagents and STANBIO Laboratory Reagents. It is used to monitor various physiological diseases or conditions. Precision Systems Inc will distribute, recommend and sales STANBIO Reagents without any modification of STANBIO packaging using PSI Applications sheets.

Bill Haden, Vice President
December 16. 2002

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K024182