AUG 2 3 2002

G. Conclusions:

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

K022072

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

Medical Analysis Systems
5300 Adolfo Road
Camarillo, CA 93012

Proprietary Name:

ANALETTE™
Medical Analysis Systems Reagents:
Calcium,
Creatinine
Phosphorus
Albumin
Total Protein
Glucose
Urea Nitrogen
Magnesium
Creatine Kinase
Alkaline Phosphatase
Carbon Dioxide
Amylase
Cholesterol(includes HDL)
Triglycerides
Total Bilirubin
Direct Bilirubin
Uric Acid
Lactate Dehydrogenase L
Lactate Dehydrogenase P
Alanine Aminotransferase
Aspartate Aminotransferase
Gamma Glutamyl Transferase
Chloride

K022072

Lipase

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
	Carbon Dioxide	862.1160
	Amylase	862.1070
	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
	Lactate Dehydrogenase P	862.1440
	Alanine Aminotransferase	862.1030
	Aspartate Aminotransferase	862.1100
	Gamma Glutamyl Transferase	862.1360
	Lipase	862.1465
	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® 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

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 23 2002

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

Re: k022072
Trade/Device Name: Precision Systems Analette Chemistry Analyzer & Medical Analysis Systems Reagents
Regulation Number: 21 CFR 862.1035
Regulation Name: Albumin test system
Regulatory Class: Class II
Product Code: CIX; CKA; CIT; CGS; CGA; CJY; CGX; CFJ; CJE; KHS; CIG; CEK; JFJ; CGZ; JQB; CDQ; CHH; JGJ; JGY; CET; CEO; KNK
Dated: June 14, 2002
Received: June 26, 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 the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 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 advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained 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
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510k K022072
PRODUCT: PRECISION SYSTEMS ANALETTE CHEMISTRY ANALYZER & MEDICAL ANALYSIS SYSTEMS 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, Carbon Dioxide, Amylase, Cholesterol(includes HDL), Triglycerides, Total Bilirubin, Direct Bilirubin, Uric Acid, Lactate Dehydrogenase L, Lactate Dehydrogenase P, Alanine Aminotransferase, Aspartate Aminotransferase, Gamma Glutamyl Transferase, Lipase, 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 and Medical Analysis Systems Reagents. It is used to monitor various physiological diseases or conditions. Precision Systems Inc will distribute, recommend and sales MAS Reagents without any modification of MAS packaging using PSI Applications sheets.

Bill Haden, Vice President
June 12, 2002

for Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K022077

prescription use X
(per 21 CFR 801.109)