May 9, 2018

Sekisui Medical Co., Ltd.
% Shelly Harris
Director of Regulatory Affairs
Sekisui Diagnostics, LLC
6659 Top Gun Drive
San Diego, California 92121

Re: K173202
Trade/Device Name: CP3000 Coagulation analyzer, Coagpia AT Reagent, Coagpia Calibrator, Coagpia Control Set
Regulation Number: 21 CFR 864.5425
Regulation Name: Multipurpose system for in vitro coagulation studies
Regulatory Class: Class II
Product Code: JPA, JBQ, JIX, GGN
Dated: March 23, 2018
Received: April 9, 2018

Dear Shelly Harris:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Leonthena R. Carrington -S

Lea Carrington
Director
Division of Immunology
and Hematology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173202

Device Name
CP3000 Coagulation Analyzer, Coagpia AT Reagent, Coagpia Calibrator, and Coagpia Control Set

Indications for Use *(Describe)*

CP3000 analyzer
The CP3000 is a fully automated, random-access in vitro blood coagulation analyzer intended for use by healthcare professionals in the clinical laboratory. The CP3000 analyzer is designed to process plasma samples photometrically using chromogenic assays.

Coagpia AT Reagent
Coagpia AT Reagent is intended for the quantitative determination of antithrombin (AT) activity in human 3.2% citrated venous plasma. The reagent is intended for use on Sekisui CP3000 analyzers by trained laboratory personnel in clinical laboratories. For in vitro diagnostic use.

Coagpia Calibrator
The Coagpia Calibrator is intended for use as a calibration plasma for the following Sekisui coagulation assay on Sekisui CP3000 analyzers by trained laboratory personnel in clinical laboratories. For in vitro diagnostic use.
- Coagpia AT Reagent

Coagpia Control Set
The Coagpia Control Set contains 2 levels of assayed plasma intended for the quality control of the following Sekisui coagulation assay on Sekisui CP3000 analyzers by trained laboratory personnel. For in vitro diagnostic use.
- Coagpia AT Reagent

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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SECTION 5 510(K) SUMMARY

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of 21 CFR §807.92. This is a Traditional 510(k).

5.1. SPONSOR/APPLICANT INFORMATION AND DATE [807.92(A) (1)]

Owner/Manufacturer Name and Address:	Sekisui Medical Co., Ltd. 1-3, Nihonbashi, 2-Chome Chuo-ku, Tokyo 103-0027, Japan FEI Number: 3006769061 Establishment Registration Number: 3003539867
Submitter Name and Address:	Sekisui Medical Co., Ltd. 1-3, Nihonbashi, 2-Chome Chuo-ku, Tokyo 103-0027, Japan FEI Number: 3006769061 Establishment Registration Number: 3003539867
Contact Person:	Shelly Harris Director of Regulatory Affairs Sekisui Diagnostics, LLC (858) 777-2627 Michelle.harris@sekisui-dx.com
Application correspondent:	Shelly Harris Director of Regulatory Affairs Sekisui Diagnostics, LLC (858) 777-2627 Michelle.harris@sekisui-dx.com
Date Summary prepared:	May 3, 2018

5.2. DEVICE NAME AND CLASSIFICATION [807.92 (A)(2)]

Trade Name	Common Name	Classification Name	Classification	Product Code
CP3000	Coagulation Analyzers	Multipurpose system for in vitro coagulation studies	Class II 21 CFR 864.5425	JPA
Coagpia AT Reagent	Antithrombin assay reagent	Antithrombin III assay	Class II 21 CFR 864.7060	JBQ
Coagpia Calibrator	Calibrator (Standard Human Plasma)	Calibrator, multi-analyte mixture	Class II 21 CFR 864.5425	JIX
Coagpia Control Set	Control Plasma	Plasma, Coagulation Control	Class II 21 CFR 864.5425	GGN

5.3. IDENTIFICATION OF LEGALLY MARKETED PREDICATE DEVICES [807.92(A)(3)]

Trade Name	Predicate Device	Predicate 510(k) Number
CP3000	ACL TOP	K160276- ACL TOP 700 LAS
Coagpia AT Reagent	HemosIL Liquid Antithrombin	K062431
Coagpia Calibrator	HemosIL Calibration Plasma	K041905
Coagpia Control Set	HemosIL Normal Control Assayed HemosIL Low Abnormal Control Assayed	K021023 K021024

5.4. DEVICE DESCRIPTION [807.92 (A)(4)]

Trade Name	Device Description
CP3000	The CP3000 is designed for easy-to-use, rapid in-vitro blood coagulation testing on citrated human plasma. The CP3000 system is capable of performing the chromogenic methodologic assay, giving the user the ability to perform analysis for both direct hemostasis measurements and calculated parameters. For these assay methodologies, the analyzers employs two photometric detection methods: light scattering and absorbance. The light scattering method uses light emitting diodes at a wavelength of 660 nm, and the absorbance method uses a halogen lamp with filters providing wavelengths at 405/570/730 nm.
Coagpia AT Reagent	Coagpia AT Reagent is intended for the quantitative determination of antithrombin (AT) activity in human plasma on the CP3000 analyzers. The reagent is supplied in a kit of 2 x 10 mL of Reagent 1 and 1 x 10mL of Reagent 2. Both reagents are liquid and do not require any preparation prior to use.
Coagpia Calibrator	The Coagpia Calibrator is supplied as 10 vials of lyophilized human plasma and is suitable for the calibration of the antithrombin activity assay using Coagpia AT Reagent on the CP3000 coagulation analyzers.

Trade Name	Device Description
Coagpia Control Set	The Coagpia Control Set is supplied as10 vials of lyophilized human plasma; 5 vials of Level 1 Control and 5 vials of Level 2 Control and is suitable for use with the antithrombin activity assay using Coagpia AT Reagent on the CP3000 analyzers.

5.5. INTENDED USE [807.92 (A)(5)]

Trade Name	Intended Use
CP3000	The CP3000 is a fully automated, random-access in vitro blood coagulation analyzer intended for use by healthcare professionals in the clinical laboratory. The CP3000 analyzer is designed to process plasma samples photometrically using chromogenic assays.
Coagpia AT Reagent	Coagpia AT Reagent is intended for the quantitative determination of antithrombin (AT) activity in human 3.2% citrated venous plasma. The reagent is intended for use on Sekisui CP3000 analyzers by trained laboratory personnel in clinical laboratories. For in vitro diagnostic use.
Coagpia Calibrator	The Coagpia Calibrator is intended for use as a calibration plasma for the following Sekisui coagulation assay on Sekisui CP3000 analyzers by trained laboratory personnel in clinical laboratories. For in vitro diagnostic use. • *Coagpia AT Reagent*
Coagpia Control Set	The Coagpia Control set contains 2 levels of assayed plasma intended for the quality control of the following Sekisui coagulation assay on Sekisui CP3000 analyzers by trained laboratory personnel. For in vitro diagnostic use. • *Coagpia AT Reagent*

5.6. TECHNOLOGICAL SIMILARITIES AND DIFFERENCES TO THE PREDICATE [807.92 (A)(6)]

The CP3000 coagulation analyzers and Coagpia AT Reagent, Coagpia Calibrator and Coagpia Control Set included in the submission each has a unique predicate device, as described in the tables below.

5.6.1 CP3000 Coagulation Analyzers

Characteristic	New Device	Predicate Device

	CP3000 (CTS and non-CTS) (There will be 2 catalog codes for CTS and non-CTS) (Proposed)	ACL TOP 700 (CTS and non-CTS) (K160276)
Options	Available with closed tube sampling (CTS) function	Same
Analytes	Multiple	Same
Intended Use and Indications for Use	The CP3000 is a fully automated, random-access in vitro blood coagulation analyzer intended for use by healthcare professionals in the clinical laboratory. The CP3000 analyzer is designed to process plasma samples photometrically using chromogenic assays.	The ACL TOP is a bench top, fully automated, random access analyzer designed specifically for in vitro diagnostic clinical use in the hemostasis laboratory for coagulation and/or fibrinolysis testing in the assessment of thrombosis and/or hemostasis. The system provides results for both direct hemostasis measurement and calculated parameter.
Method Types	• Chromogenic	• Coagulometric (turbidimetric) measurement • Chromogenic (absorbance) measurement • Immunological measurement
Interface	• Touch screen operation • Windows 7 Operating System	• Touch screen operation • Windows XP Operating System
Detection	Photometric • Absorbance • Light scattering	Photometric • Absorbance
Wavelengths	• 405 nm • 570 nm • 660 nm • 730 nm	• 405 nm • 671 nm
Throughput (non-CTS)	Up to 400 clotting tests/hour	Up to 330 PT and APTT tests/hour
Reagent Handling	• Refrigerated on board • Internal bar code sample identification	Same

5.6.2 Coagpia AT Reagent

Characteristic	New Device	Predicate Device

	Coagpia AT Reagent (Proposed)	**HemosIL Liquid Antithrombin (K062431)**
Analyte	Antithrombin	Same
Indications for Use	Coagpia AT Reagent is intended for the quantitative determination of antithrombin (AT) activity in human 3.2% citrated venous plasma. The reagent is intended for use on Sekisui CP3000 analyzers by trained laboratory personnel in clinical laboratories. For in vitro diagnostic use.	HemosIL Liquid Antithrombin is an automated chromogenic assay for the quantitative determination of Antithrombin in human citrated plasma as an aid in the diagnosis of hereditary and acquired Antithrombin deficiency and to monitor Antithrombin substitution therapy. This in vitro diagnostic test is based on a synthetic chromogenic substrate and on Factor Xa inactivation. As a consequence, it is specific and not influenced by Heparin Cofactor II. Antithrombin levels in patient plasma are measured automatically on IL Coagulation Systems.
Reagent State	Liquid, ready to use	Same
Method	Chromogenic	Same
Detection	Photometric	Same
Key Components	• Factor Xa (bovine) • Heparin • N-Acetyl-D-arginyl-glycyl-L-arginyl-p-nitroanilide dihydrochloride (chromogenic substrate)	• Factor Xa (bovine) • Heparin • N-α-Z-D-Arg-Gly-Arg-pNA·2HCl (chromogenic substrate)
Sample Type	Human citrated plasma	Human citrated plasma
Expected Values	89 -131%	83 - 128%
Repeatability	0.7-2.9%	2.2 – 7.4%
Within Laboratory	1.1-5.8%	3.1 – 8.6%

Characteristic	New Device Coagpia AT Reagent (Proposed)	Predicate Device HemosIL Liquid Antithrombin (K062431)
Precision		
Clinical Reportable Range (CRR)	14-150%	10 – 150%

5.6.3 Coagpia Calibrator

Characteristic	New Device	Predicate Device
	Coagpia Calibrator (Proposed)	**HemosIL Calibration plasma (K041905)**
Intended Use and Indications for Use	The Coagpia Calibrator is intended for use as a calibration plasma for the following Sekisui coagulation assay on Sekisui CP3000 analyzers by trained laboratory personnel in clinical laboratories. For in vitro diagnostic use. • Coagpia AT Reagent	HemosIL Calibration plasma is intended for the calibration of coagulation assays on IL and ELECTRA Coagulation Systems. Used for the determination of PT, Fibrinogen, Single Factors, von Willebrand Factor, Antithrombin, Plasminogen, Plasmin Inhibitor, Protein C, Protein S, and as a reference plasma for APTT and TT.
Format	Lyophilized	Same
Calibrator Type	Antithrombin	Fibrinogen, Antithrombin, PT, Single Factors, von Willebrand Factor, Plasminogen, Plasmin Inhibitor, Protein C, Protein S, and as a reference plasma for APTT and TT.
Key Components	Human plasma	Same

5.6.4 Coagpia Control Set

Characteristic	New Device	Predicate Device	
	Coagpia Control Set (Proposed)	**HemosIL Normal Control Assayed (K021023)**	**HemosIL High Abnormal Control Assayed (K021024)**
Intended Use and Indications for Use	The Coagpia Control set contains 2 levels of assayed plasma intended for the quality control of the following Sekisui coagulation assay on Sekisui CP3000 analyzers by trained laboratory personnel. For in vitro diagnostic use. • Coagpia AT Reagent	HemosIL Normal Control ASSAYED is intended for the quality control of coagulation assays in the normal range on IL Coagulation and ELECTRA Systems. The normal control is prepared using human citrated plasma from Health donors. Values for all analytes are	HemosIL High Abnormal Control ASSAYED is intended for the quality control of coagulation assays in the high abnormal range on IL Coagulation and ELECTRA Systems. The High Abnormal Control is prepared using human citrated plasma from healthy donors (not heparinized plasma or plasma samples under oral anticoagulation

		within the normal range.	therapy) and modified to stimulate an abnormal coagulation sample. Values for all analytes are in the high abnormal range.
Format	Lyophilized	Same	Same
Key Components	Human plasma	Same	Same

5.7. SUMMARY OF NON-CLINICAL PERFORMANCE DATA [807.92 (B)(1)]

5.7.1 CP3000 Coagulation analyzers

The CP3000 analyzers were successfully tested for electrical safety, emissions and immunity according to the following standards:

Description	Standard	Title
Electrical Safety Testing	IEC 61010-1	Safety requirements for electrical equipment for measurement, control and laboratory use. Part 1: General requirements
	IEC 61010-2-081	Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes
	IEC 60825-1	Safety of laser products – Part 1: Equipment classification and requirements
	IEC61010-2-101	Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-101. Particular requirements for *in vitro* diagnostic (IVD) medical equipment
Emission	IEC 61326-2-6	Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements – In vitro diagnostic (IVD) medical equipment
	CISPR 11	Industrial, scientific and medical equipment – Radio-frequency disturbance characteristics – Limits and methods of measurement
	IEC 61000-3-2	Electromagnetic compatibility (EMC) – Part 3-2: Limits – Limits for harmonic current emissions
	IEC 61000-3-3	Electromagnetic compatibility (EMC) – Part 3-3: Limits – Limitation of voltage changes, voltage fluctuations and flicker in public low – voltage supply systems, for equipment with rated current ≤16 A per phase and not

Description	Standard	Title
		subject to conditional connection
Immunity	IEC 61326-2-6	Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements – In vitro diagnostic (ICD) medical equipment
	IEC 61000-4-2	Electromagnetic compatibility (EMC) – Part 4-2: Testing and measurement techniques – Electrostatic discharge immunity test
	IEC 61000-4-3	Electromagnetic compatibility (EMC) – Part 4-3: Testing and measurement techniques – Radiated, radio-frequency, electromagnetic field immunity test
	IEC 61000-4-4	Electromagnetic compatibility (EMC) – Part 4-4: Testing and measurement techniques – Electrical fast transient/burst immunity test
	IEC 61000-4-5	Electromagnetic compatibility (EMC) – Part 4-5: Testing and measurement techniques – Surge immunity test
	IEC 61000-4-6	Electromagnetic compatibility (EMC) – Part 4-6: Testing and measurement techniques – Immunity to conducted disturbances, induced by radio-frequency fields
	IEC 61000-4-8	Electromagnetic compatibility (EMC) – Part 4-8: Testing and measurement techniques – Power frequency magnetic field immunity test
	IEC 61000-4-11	Electromagnetic compatibility (EMC) – Part 4-11: Testing and measurement techniques – Voltage dips, short interruptions and voltage variations immunity tests

5.7.2 Coagpia AT Reagent

Precision

Precision studies were performed according to CLSI EP5-A3. Repeatability (Within-Run precision), Between-Run precision, Between-day precision, Between-lot precision, Between Instrument, and Total precision were determined using six samples tested in duplicate, twice per day on 20 non-consecutive days on three CP3000 analyzers using three lots of Coagpia AT Reagent. The following results were demonstrated:

Sample	Mean	Repeatability		Between Run		Between Day		Between Lot		Within Laboratory		Between Instrument		Total	
		SD	**CV**	**SD**	**CV**	**SD**	**CV**	**SD**	**CV**	**SD**	**CV**	**SD**	**CV**	**SD**	**CV**
Sample 1	31.1	0.9	2.9%	1.6	5.1%	0.0	0.0%	0.3	1.0%	1.8	5.8%	1.5	4.8%	2.4	7.7%
Sample 2	54.6	0.9	1.6%	1.4	2.6%	0.2	0.4%	0.2	0.4%	1.7	3.1%	1.5	2.7%	2.3	4.2%
Sample 3	79.9	0.8	1.0%	1.4	1.8%	0.0	0.0%	0.3	0.4%	1.6	2.0%	1.1	1.4%	2.0	2.5%
Sample 4	106.5	1.0	0.9%	1.3	1.2%	0.0	0.0%	0.5	0.5%	1.7	1.6%	1.1	1.0%	2.1	2.0%
Sample 5	130.8	0.9	0.7%	1.1	0.8%	0.1	0.1%	0.5	0.4%	1.5	1.1%	0.8	0.6%	1.7	1.3%
Sample 6	151.2	3.2	2.1%	2.8	1.9%	0.0	0.0%	0.5	0.3%	4.3	2.8%	2.8	1.9%	5.1	3.4%
Criteria			≤10%		≤10%		≤10%		≤10%		≤10%		≤15%		≤15%
Pass/Fail			Pass		Pass		Pass		Pass		Pass		Pass		Pass

Analytical Sensitivity

Limit of Quantitation:

Limit of Quantitation (LOQ) represents the lowest amount of AT that can be detected reliably. Five natural plasmas at concentrations near the lower limit of Reportable Range were measured in quadruplicate using three lots of Coagpia AT Reagent on two CP3000 analyzers. Measurement has been conducted for four days for a total of eighty replicates per analyzer (5 samples x quadruplicate x 4 days). LOQ was determined at the level where the calculated total error estimate falls within the defined goal (total error ≤15%). The Limit of Quantitation was determined to be 11%.

Limit of Blank:

Limit of blank (LOB) is the highest concentration likely to be measured for a blank sample. Five analyte-free plasmas and five natural plasmas at concentrations near the lower limit of Reportable Range were measured in quadruplicate using three lots of Coagpia AT Reagent on two CP3000 analyzers. Results were processed and analyzed following CLSI Guidance EP17-A. The Limit of blank was determined to be 3%.

Limit of Detection:

Limit of detection (LOD) is the lowest concentration of an analyte that is reliably detected. Five analyte-free plasmas and five natural plasmas at concentrations near the lower limit of Reportable Range were measured in quadruplicate using three lots of Coagpia AT Reagent on two CP3000 analyzers. Results were processed and analyzed following CLSI Guidance EP17-A. The Limit of Detection was determined to be 5%.

Linearity:

High AT plasma (pooled plasma) was diluted with AT deficient plasma to create the sample concentration required for this evaluation. The dilution series was prepared above and below the anticipated linear range of the test method as recommended by CLSI EP6-A. Each sample was measured in quadruplicate using three lots of Coagpia AT Reagent. Linearity range was determined at the level where the calculated allowable non linearity estimate falls within the defined goal (allowable non linearity ≤20%). The data demonstrate a Linear Range of 14 – 140%.

Clinical Reportable Range:

A clinical reportable range study was conducted to determine the upper limit of the measurable range of the assay. The Auto Dilution (auto-rerun as defined in the system software) function was turned on for this study. High AT plasma (pooled plasma) was diluted with AT deficient plasma to create the sample concentration required for this evaluation. Each sample was measured in quadruplicate using three lots of Coagpia AT Reagent. % Difference (Recovery) to the theoretical value has been calculated for each measurement result. Measurement range of which % difference falls within ±10% has been determined. The data demonstrate measurement range up to 179% which met the design goal of 150%. The following Table summarizes the Analytical Data.

Analytical Data Summary					
AT Lot #	**LOQ**	**LOB**	**LOD**	**Lower limit of Linear Range**	**Upper limit of Reportable Range**
IUO001	11%	3%	4-5%	10.8 %	182%
IUO002	11%	2%	4%	14.0 %	179%
IUO003	11%	3%	4-5%	11.0 %	182%

Based on this result, the Clinical Reportable Range (CRR) of the Coagpia AT Reagent on CP3000 analyzers have been verified from 14% to 179%. The CRR claim is 14% to 150%.

Analytical Specificity (Endogenous and Exogenous Interference)

Interference studies were performed according to the paired difference method reference in CLSI EP7A2. The Coagpia AT Reagent is insensitive to the following substances:

- Hemoglobin concentration up to 700mg/dL
- Triglyceride concentration up to 2000mg/dL
- Unconjugated Bilirubin concentration up to 100mg/dL
- Conjugated Bilirubin concentration up to 100mg/dL
- α2-Macroglobulin concentration up to 500mg/dL
- α1-antitrypsin concentration up to 600mg/dL
- Unfractionated heparin concentration up to 8.0IU/mL
- Low Molecular Weighted heparin concentration up to 8.0IU/mL
- Bivariludin concentration of to 30μg/mL
- Dabigatran concentration up to 1000ng/mL
- Argatroban concentration up to 2500ng/mL
- Rivaroxaban concentration up to 25ng/mL

5.7.3 Coagpia Calibrator

Precision

Precision studies were performed according to CLSI EP5-A3. Repeatability (Within-Run precision), Between-Run precision, Between-day precision, Between-lot precision, Within-laboratory precision, and Total precision were determined using three lots of Coagpia Calibrator tested in in duplicate, twice per day on 20 non-consecutive days on three CP3000 analyzers using three lots of Coagpia AT Reagent calibrated with in-house primary reference standard. The following result were demonstrated:

Mean	**Within Run**		**Between Run**		**Between Day**		**Between Lot**		**Within Laboratory**		**Between Instrument**		**Total**	
	SD	**CV**	**SD**	**CV**	**SD**	**SD**	**SD**	**CV**	**SD**	**CV**	**SD**	**CV**	**SD**	**CV**
103.1	0.8	0.8%	1.5	1.5%	0.0	0.0%	2.4	2.3%	2.9	2.8%	1.5	1.5%	3.3	3.2%
Criteria		≤10%		≤10%		≤10%		≤10%		≤10%		≤15%		≤15%
Pass/Fail		Pass		Pass		Pass		Pass		Pass		Pass		Pass

5.7.4 Coagpia Control Set

Precision

Precision studies were performed according to CLSI EP5-A3. Repeatability (Within-Run precision), Between-Run precision, Between-day precision, Between-lot precision, Within-laboratory precision, and Total precision were determined using three lots of Coagpia Control Set tested in in duplicate, twice per day on 20 non-consecutive days on three CP3000 analyzers using three lots of Coagpia AT Reagent calibrated with in-house primary reference standard. The following result were demonstrated:

Coagpia Control Set	Mean	Within Run		Between Run		Between Day		Between Lot		Within Laboratory		Between Instrument		Total	
		SD	CV	SD	CV	SD	CV	SD	CV	SD	CV	SD	CV	SD	CV
Level 1	99.5	0.9	0.9%	1.4	1.4%	0.3	0.3%	1.1	1.1%	2.1	2.1%	1.5	1.5%	2.6	2.6%
Level 2	31.8	0.8	2.5%	1.4	4.4%	0.6	1.9%	0.9	2.8%	1.9	6.0%	1.1	3.5%	2.2	6.9%
Criteria			≤10%		≤10%		≤10%		≤10%		≤10%		≤15%		≤15%
Pass/Fail			Pass		Pass		Pass		Pass		Pass		Pass		Pass

5.8. SUMMARY OF CLINICAL PERFORMANCE CHARACTERISTICS

Method comparison with predicate device:

A method comparison study was performed to compare the performance of the CP3000 with Coagpia AT Reagent to the predicate device, Instrumentation Laboratories (IL) ACL TOP 700 with HemosIL Liquid Antithrombin. The study was conducted at three (3) externals sites utilizing left-over, prospectively collected, citrated plasma samples. A total of 482 samples were analyzed. Results were analyzed using Deming regression. All results met the acceptance criteria. Acceptance criteria: Slope 0.90 to 1.10; Correlation Coefficient (r) $\geq$ 0.90. The following table summarizes the regression results:

Instrument	N	Slope	Intercept	r
CP3000	482	1.012	0.4	0.9909

Normal reference range:

A normal reference interval study was conducted to determine the normal reference range for the Coagpia AT assay. The study was conducted at three (3) external sites utilizing fresh citrated plasma samples collected from consented, apparently healthy adult volunteers. A total of 179 samples were analyzed. The reference range was established by calculating the non-parametric 95% confidence interval (2.5^{th} to 97.5^{th} percentiles). The mean of the reference range was 108.9% and the central 95% range was 89% to 131%. The following table summarizes the results for the normal reference interval:

Reference Interval	Lower Limit	Upper Limit
Antithrombin	89%	131%

Reproducibility:

The reproducibility study utilized a 5x2x3x3 design (five non-consecutive days, two runs per day, three replicates per run at three sites). Three lots of Coagpia AT Reagent were evaluated for repeatability (within-run) and total reproducibility. The mean, SD and %CV were calculated for each sample tested. For repeatability, the %CV for all six levels ranged from 0.8% to 3.8% which met the acceptance criteria of $\leq$ 10%. For total reproducibility, the %CV for all six levels ranged from 1.1% to 7.5% which met the acceptance criteria of $\leq$ 15%. The following table summarizes the reproducibility results for the Coagpia AT Reagent for all sites combined:

			Within-Run		Total	
Sample	**N**	**Mean**	**SD**	**%CV**	**SD**	**%CV**
Level 1	270	30.0	1.15	3.8%	2.26	7.5%
Level 2	270	51.7	1.00	1.9%	2.02	3.9%
Level 3	270	77.5	0.86	1.1%	1.45	1.9%
Level 4	270	102.8	0.98	1.0%	1.43	1.4%
Level 5	270	122.7	1.03	0.8%	1.36	1.1%
Level 6	270	145.3	2.01	1.4%	3.06	2.1%

Three lots of Coagpia Control Set and three lots of Coagpia Calibrator were evaluated for repeatability (within-run) and total reproducibility. The mean, SD and %CV were calculated for each sample tested. For repeatability, the %CV ranged from 0.8% to 3.2% which met the acceptance criteria of ≤ 10%. For total reproducibility, the %CV ranged from 2.7% to 6.1% which met the acceptance criteria of ≤ 15%. The following table summarizes the reproducibility results for the Coagpia Control Set and Coagpia Calibrator for all sites combined:

			Within-Run		Total	
Sample	**N**	**Mean**	**SD**	**%CV**	**SD**	**%CV**
Control Level 1	270	99.4	0.84	0.8%	2.70	2.7%
Control Level 2	270	33.3	1.08	3.2%	2.03	6.1%
Calibrator	270	102.2	1.00	1.0%	3.07	3.0%

5.9. CONCLUSION

Coagpia AT Reagent on CP3000 analyzers system was shown to be substantially equivalent to the HemosIL liquid Antithrombin assay (K062431) on ACL TOP700 System (K160276).