

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY**

A. 510(k) Number:

k083896

B. Purpose for Submission:

Clearance of new instrument

C. Manufacturer and Instrument Name:

Trinity Biotech Destiny Max

D. Type of Test or Tests Performed:

Qualitative or Quantitative coagulation Testing – Prothrombin Time (PT), activated Partial Thromboplastin Time (APTT), Fibrinogen, Thrombin Time (TT), Factor assays, Antithrombin (AT), Protein C, Antiplasmin, Heparin, Plasminogen, PAI-1, Tissue Plasminogen, Activator, D-dimer, free Protein S, von Willebrand Factor Antigen

E. System Descriptions:

1. Device Description:

The Destiny Max instrument performs hemostasis testing using human samples. The system is comprised of an instrument that performs the assay testing and a Personal Computer. The Destiny Max is a high through put instrument with cap-piercing capability and Graphic User Interface (GUI) software that provides the user the capability to order tests, visualize and print the results.

2. Principles of Operation:

The Destiny Max is a coagulation analyzer that performs clotting, chromogenic and immuno-turbidimetric coagulation testing. The analytic processes are performed inside plastic disposable cuvette trays. Cuvettes are extracted from the supply and travel along a transport system where they are pre-heated. Sample is pipetted from an open or closed tube, and then a reagent arm adds the appropriate reagent. The cuvettes are then moved to the analytical section of the transport system where the measurement (mechanical and/or optical) takes place.

The mechanical measurement module of the Destiny Max system performs the measurement of clotting times using an electromechanical method. There are eight mechanical measurement channels, which gives the system the capability to perform eight simultaneous clotting time measurements of any type.

The optical measurement module of the Destiny Max system is an electro-optical device that monitors the transmission of changes in the optical reaction cuvette wells. This module is made of solid state light sources at four different wavelengths, optical light guides, and detectors. The data points gathered during the measurement process are used to perform optical clotting time measurements, chromogenic measurements or immuno-turbidimetric measurements. Once the analytical process is complete, the cuvettes continue to the waste area where they are stored for manual removal by the operator.

3. Modes of Operation:

Random access; multi-tasking (an unlimited number of tests may be programmed at one time)

4. Specimen Identification:

Barcode reader

5. Specimen Sampling and Handling:

Sample is aspirated and dispensed using the cap-piercing probe. For samples that must be prediluted, the sample will be aspirated from the aliquot cuvette and transferred to the predilution cuvette, diluted, and transferred to the measuring cuvette. For samples loaded in Eppendorf cups on the Eppendorf Sample Tray, the sample will be pipetted directly into the measuring cuvette.

6. Calibration:

Results are calculated into concentration or activity units with the use of stored calibration curves. Up to 12 calibration curve points/calibrator and up to 5 calibrators per assay can be stored. There are several ways the Destiny Max can prepare a calibration curve:

- 1) Automatic dilutions of a single calibrator plasma
- 2) Automatic dilutions of a single calibrator plasma with a blank added
- 3) A series of dilutions manually prepared
- 4) Using a calibration set containing several calibrator plasmas

7. Quality Control:

- 1000 result positions per control level file
- Levy-Jennings-like graphic screen display of up to 120 results on each control for each test
- Operator alert on screen and result printout when QC error occurs
- Westgard rules or other laboratory definable result criteria evaluation

8. Software:

FDA has reviewed applicant's Hazard Analysis and Software Development processes for this line of product types:

Yes X or No

F. Regulatory Information:

1. Regulation section:

21 CFR 864.5425; Multipurpose System for In Vitro Coagulation Studies

2. Classification:

Class II

3. Product code:

JPA; Multipurpose System for In Vitro Coagulation Studies

4. Panel:

81 Hematology

G. Intended Use:

1. Indication(s) for Use:

The Destiny Max Coagulation Analyzer is a multipurpose system for in vitro coagulation studies consisting of one automated instrument and its associated reagent and controls. The system is used to perform a series of coagulation studies and coagulation factor assays.

2. Special Conditions for Use Statement(s):

Prescription Use

H. Substantial Equivalence Information:

1. Predicate Device Name(s) and 510(k) numbers:

Amax Destiny™ Coagulation Analyzer (k021162)

2. Comparison with Predicate Device:

Similarities		
Item	Device	Predicate
Intended use	Automate coagulation instrument that performs clotting, mechanical, and imunoturbic assays	same
Min Sample Size requirements	150 µL (optical) 75 µL (mechanical)	same
Sample Barcode ID	Yes	same

Differences		
Item	Device	Predicate
Cap piercing	Yes	no
PT throughput	350	180
PTT/FIB/PT	300	110

I. Special Control/Guidance Document Referenced (if applicable):

CLSI EP-5A2, Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline.

EP06-A “Evaluation of the Linearity of Quantitative Measurement: Approved Guideline, 2nd Ed., 04/2003”

EP07-A2, “Interference Testing in Clinical Chemistry; Approved Guideline, 2nd Ed., 11/23/2005”

EP9-A2; Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline

EP17-A, “Protocols for Determination of Limits of Detection and Quantitation; Approved Guideline

H21-A5, “Collection, Transport and Processing of Blood Samples for Testing Plasma-based Coagulation Assays and Molecular Hemostasis Assays; Approved Guideline-Fifth Edition”, 2008

EN 60601:2007, “Medical Electrical Equipment Part 1-2 General Requirement for Basic Safety and Essential Performance

ASTM E1381, “Low Level Communication Protocol”

ASTM E1394, “High Level Communication Protocol”

WEEE EEC2002/96/CE, “Waste Electrical and Electronic Equipment Directive”

RoHs 2002/96/E, “Restriction of Certain Hazardous Substances in Electrica and Electronic Equipment”

J. Performance Characteristics:

1. Analytical Performance:

a. *Accuracy:*

A three site accuracy study was conducted to demonstrate correlation to the predicate device. Samples were collected in 3.2% sodium citrate and were selected from normal as well as the intended patient population. A minimum of 80 samples per test were run at each site.

Assay	N	Slope	Intercept	R
TriniCLOT PT HTF Optical Mode Seconds	204	1.09	-2.30	0.98
TriniCLOT PT HTF Mechanical Mode Seconds	217	1.08	-1.87	0.99
TriniCLOT Excel S Optical Mode Seconds	195	1.01	-0.7	1.00
TriniCLOT Excel S Mechanical Mode Seconds	205	1.07	-1.30	0.99
TriniCLOT APTT S Optical Mode Seconds	192	0.98	-1.99	0.98

Assay	Site	N	Slope	Intercept	R
TriniCLOT Excel S Optical Mode Seconds	1	77	1.03	-1.61	1.00
TriniCLOT Excel S Optical Mode Seconds	2	43	0.99	-1.36	1.00
TriniCLOT Excel S Optical Mode Seconds	3	75	1.01	-0.05	1.00
TriniCLOT Excel S Mechanical Mode Seconds	1	78	1.09	-2.08	1.00
TriniCLOT Excel S Mechanical Mode Seconds	2	49	1.04	-1.29	1.00
TriniCLOT Excel S Mechanical Mode Seconds	3	78	1.13	-1.43	1.00
TriniCLOT APTT S Optical Mode Seconds	1	63	0.97	-1.82	0.99
TriniCLOT APTT S Optical Mode Seconds	2	49	0.87	1.57	0.93
TriniCLOT APTT S Optical Mode Seconds	3	80	1.03	-3.11	0.99
TriniCLOT APTT S Mechanical Mode Seconds	1	67	0.91	2.65	0.99
TriniCLOT APTT S Mechanical Mode Seconds	2	57	1.05	-2.08	0.97
TriniCLOT APTT S Mechanical Mode Seconds	3	86	1.01	-0.27	0.98
TriniCLOT Thrombin Time Mechanical Mode Seconds	1	50	1.21	-3.35	0.97
TriniCLOT Thrombin Time Mechanical Mode Seconds	2	19	0.89	0.91	0.96
TriniCLOT Thrombin Time Mechanical Mode Seconds	3	73	1.04	-0.37	0.99
TriniCLOT Fibrinogen Optical Mode mg/dL	1	80	0.90	15.56	1.00
TriniCLOT Fibrinogen Optical Mode mg/dL	2	69	1.02	-5.45	0.98
TriniCLOT Fibrinogen Optical Mode mg/dL	3	68	0.73	71.70	0.95
TriniCLOT Fibrinogen Mechanical Mode mg/dL	1	80	0.86	44.28	0.99
TriniCLOT Fibrinogen Mechanical Mode mg/dL	2	65	1.10	-21.04	0.97
TriniCLOT Fibrinogen Mechanical Mode mg/dL	3	60	0.91	49.84	0.94
TriniCLOT FVII Optical Mode %	1	77	0.94	0.30	0.98
TriniCLOT FVII Optical Mode %	2	81	0.99	-1.65	0.98
TriniCLOT FVII Optical Mode %	3	57	0.78	8.56	0.98
TriniCLOT FVII Mechanical Mode %	1	77	0.98	3.91	0.96
TriniCLOT FVII Mechanical Mode %	2	82	0.89	10.35	0.96
TriniCLOT FVII Mechanical Mode %	3	58	0.82	6.87	0.96
TriniCLOT FIX Optical Mode %	1	117	0.84	0.92	0.88
TriniCLOT FIX Optical Mode %	2	76	1.01	-1.43	0.97
TriniCLOT FIX Optical Mode %	3	60	1.06	-6.17	0.95
TriniCLOT FIX Mechanical Mode %	1	117	0.96	3.21	0.90
TriniCLOT FIX Mechanical Mode %	2	77	0.95	1.46	0.96
TriniCLOT FIX Mechanical Mode %	3	60	0.87	2.60	0.97
TriniCHROM Antithrombin IIa %	1	80	0.98	7.87	0.99
TriniCHROM Antithrombin IIa %	2	77	0.84	4.52	0.97
TriniCHROM Antithrombin IIa %	3	80	0.95	13.62	0.99
TriniLIA D-Dimer ng/mL	1	76	0.88	182.84	0.99
TriniLIA D-Dimer ng/mL	2	68	1.28	-184.08	0.99
TriniLIA D-Dimer ng/mL	3	79	1.14	-435.84	0.98

b. *Precision/Reproducibility:*

Precision testing was performed on all assays and modes following recommendations from CLSI EP-5A. Testing was run over 5 days. On each day 4 vials of each control level (3 levels) were reconstituted and run in triplicate to give a total of 60 data points for each level of control. CV's were generally <6%. Precision for the factor levels ran a little higher; however, the values were within acceptable limits for these parameters.

c. *Linearity:*

Linearity testing was carried out following guidelines recommended in CLSI EP6-P. Assays were calibrated, and testing was performed to determine what range the signal is directly proportional to the concentration or % activity. Results are expressed as the range, and the correlation coefficient (r) for the expected vs. observed values over that range.

Assay	Range%	r
TriniClot Fibrinogen Optical Mode	64 -1400	0.993
TriniClot Fibrinogen Mechanical Mode	62-844	1.000
TriniClot Factor VII Optical Mode	1-112	0.998
TriniClot Factor VII Mechanical Mode	2 -110	0.998
TriniClot Factor IX Mechanical Mode	0-230	0.996
TriniClot Factor IX Mechanical Mode	0 -104	0.996
TriniClot Antithrombin Chromogenic Mode	0 – 150	0.998
TriniClot D-Dimer High Immunospectrophotometric Mode	70-13911	0.996

d. *Carryover:*

Not applicable

e. *Interfering Substances:*

Each assay type was tested in the presence of hemoglobin, bilirubin, lipids, and heparin, to determine the level at which the interferant affects the assay result.

Assay	Hgb mg/dL	Bili mg/dL	Lipids mg/dL	Heparin IU/mL
TriniClot PT HTF Optical Mode	150	20	100	1.0
TriniClot PT HTF Mechanical Mode	250	20	1000	1.0
TriniClot PT Excel S	225	20	100	0.7

Assay	Hgb mg/dL	Bili mg/dL	Lipids mg/dL	Heparin IU/mL
Optical Mode				
TriniClot PT Excel S Mechanical Mode	250	20	1000	0.6
TriniClot APTT S Optical Mode	200	18	100	n/a
TriniClot APTT S Mechanical Mode	250	20	1000	n/a
TriniClot Thrombin Time Mechanical Mode	250	20	1000	n/a
TriniClot Fibrinogen Optical Mode	250	20	600	n/a
TriniClot Fibrinogen Mechanical Mode	250	18	1000	n/a
TriniClot Factor VII Optical Mode	250	10	1000	n/a
TriniClot Factor VII Mechanical Mode	250	20	1000	n/a
TriniClot Factor IX Optical Mode	225	20	400	n/a
TriniClot Factor IX Mechanical Mode	225	20	1000	n/a
TriniClot Antithrombin Chromogenic Mode	250	20	1000	n/a
TriniClot D-Dimer Low Immunoturbidimetric Mode	12.5	1	0	0
TriniClot D-Dimer High Immunoturbidimetric Mode	50	20	0	1.0

2. Other Supportive Instrument Performance Data Not Covered Above:

Normal samples were analyzed for each assay, and a reference interval calculated using the mean and a 2SD range. The normal reference ranges are provided in the method applications and package inserts as guidance, however, the labeling also recommends that each laboratory establish its own ranges to reflect ethnicity and age of its own population.

The Limit of Blank (LOB) was calculated per CLSI EP17-A for the D-Dimer Test. The mean and standard deviation for 60 replicates of the diluent were calculated. It was determined that the data were approximately normally distributed, and the LOB was determined to be 60 ng/mL.

Testing was performed on the D-Dimer assay using pooled normal plasma (PNP) spiked up to >100,000ng/mL in order to determine if the assay demonstrated a high dose hook effect. No hook effect was observed.

K. Proposed Labeling:

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

L. Conclusion:

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