DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 11, 2017

ELITECHGROUP
TERRY TRIMINGHAM, REGULATORY AFFAIRS MANAGER
21720 23RD DRIVE SE, SUITE 150
BOTHELL, WA 98021

Re: K171401
Trade/Device Name: ELITech Clinical Systems BILIRUBIN TOTAL 4+1, ELITech Clinical Systems BILIRUBIN DIRECT 4+1
Regulation Number: 21 CFR 862.1110
Regulation Name: Bilirubin (total or direct) test system
Regulatory Class: II
Product Code: CIG
Dated: May 3, 2017
Received: May 12, 2017

Dear Terry Trimingham:

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 Parts 801 and 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.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kellie B. Kelm -S

for Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k171401

Device Name
ELITech Clinical Systems BILIRUBIN TOTAL 4+1
ELITech Clinical Systems BILIRUBIN DIRECT 4+1

Indications for Use *(Describe)*
ELITech Clinical Systems BILIRUBIN TOTAL 4+1 is intended for the quantitative in vitro diagnostic determination of total bilirubin in human serum and plasma on ELITech Clinical Systems Selectra Pro Series Analyzers.

ELITech Clinical Systems BILIRUBIN DIRECT 4+1 is intended for the quantitative in vitro diagnostic determination of direct bilirubin in human serum and plasma on ELITech Clinical Systems Selectra Pro Series Analyzers.

It is not intended for use in Point of Care settings.

Measurements of the levels of bilirubin (direct or total), an organic compound formed during the normal and abnormal distruction of red blood cells, are used in the diagnosis and treatment of liver, hemolytic hematological, and metabolic disorders, including hepatitis and gall bladder block.

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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510(k) Summary

ELITech Clinical Systems BILIRUBIN TOTAL 4+1
ELITech Clinical Systems BILIRUBIN DIRECT 4+1

1.	Date:	July 11, 2017
2.	Submitter:	ELITech Clinical Systems SAS Zone Industrielle 61500 SEES FRANCE
3.	Contact Person:	Terry Trimingham 21720 23rd Dr SE, Suite 150 Bothell, WA 98021 Phone: 425-482-5190 Fax: 425-482-5550 Email: t.trimingham@elitechgroup.com
4.	Device Description:	ELITech Clinical Systems BILIRUBIN TOTAL 4+1
	Classification	Class II CIG - Diazo Colorimetry, Bilirubin Clinical Chemistry 21 CFR 862.1110
	Device Description:	ELITech Clinical Systems BILIRUBIN DIRECT 4+1
	Classification	Class II CIG - Diazo Colorimetry, Bilirubin Clinical Chemistry 21 CFR 862.1110
5.	Predicate Device:	K060325 ABX Pentra Bilirubin, Total CP ABX Pentra Bilirubin, Direct CP

6. Intended Use

ELITech Clinical Systems BILIRUBIN TOTAL 4+1 :	**ELITech Clinical Systems BILIRUBIN TOTAL 4+1** is intended for the quantitative *in vitro* diagnostic determination of total bilirubin in human serum and plasma on ELITech Clinical Systems Selectra Pro Series Analyzers. Measurements of the levels of bilirubin (direct or total), an organic compound formed during the normal and abnormal distruction of red blood cells, are used in the diagnosis and treatment of liver, hemolytic hematological, and metabolic disorders, including hepatitis and gall bladder block. It is not intended for use in Point of Care settings.
ELITech Clinical Systems BILIRUBIN DIRECT 4+1 :	**ELITech Clinical Systems BILIRUBIN TOTAL 4+1** is intended for the quantitative *in vitro* diagnostic determination of total bilirubin in human serum and plasma on ELITech Clinical Systems Selectra Pro Series Analyzers. Measurements of the levels of bilirubin (direct or total), an organic compound formed during the normal and abnormal distruction of red blood cells, are used in the diagnosis and treatment of liver, hemolytic hematological, and metabolic disorders, including hepatitis and gall bladder block. It is not intended for use in Point of Care settings.

Special conditions for use statement(s):

Rx only.

This device is intended for prescription use and *in vitro* diagnostic only.

CAUTION: Federal Law restricts this device to sale by or on the order of a licensed healthcare practitioner. It is not intended for use in Point of Care settings.

Reagent Special instrument requirements:

For use with ELITech Clinical Systems Selectra Pro Series Analyzers. Performance data was obtained on the Selectra ProM Analyzer.

7. **Device Descriptions**

Both ELITech Clinical Systems BILIRUBIN TOTAL 4+1 and ELITech Clinical Systems BILIRUBIN DIRECT 4+1 are available as a kit only.

Each kit consists of a bi-reagent R1 & R2 whose composition is:

ELITech Clinical Systems BILIRUBIN TOTAL 4+1 :

Reagent 1: R1

Sulphanilic acid 29 mmol/L,

Cetrimide 29 mmol/L.

Reagent 2: R2

Sodium nitrite 11 mmol/L.

ELITech Clinical Systems BILIRUBIN DIRECT 4+1 :

Reagent 1: R1

Sulphanilic acid 29 mmol/L,

Reagent 2: R2

Sodium nitrite 11 mmol/L.

8. **Substantial Equivalence Information**

Assay (reagent)

1. Predicate Device Name

ABX Pentra Bilirubin, Total CP & ABX Pentra Bilirubin, Direct CP

2. K060325

3. Comparison with predicate ABX Pentra Bilirubin, Total CP & ABX Pentra Bilirubin, Direct CP

Similarities

Parameter	New Device ELITech Clinical Systems BILIRUBIN TOTAL 4+1 & ELITech Clinical Systems BILIRUBIN DIRECT 4+1	Predicate Device ABX Pentra Bilirubin, Total CP & ABX Pentra Bilirubin, Direct CP, K060325
Intended Use	**ELITech Clinical Systems BILIRUBIN TOTAL 4+1:** ELITech Clinical Systems BILIRUBIN TOTAL 4+1 is intended for the quantitative *in vitro* diagnostic determination of total bilirubin in human serum and plasma on ELITech Clinical Systems Selectra Pro Series Analyzers. It is not intended for use in Point of Care settings.	**ABX Pentra Bilirubin, Total CP:** ABX Pentra Bilirubin, Total CP reagent is intended for the quantitative *in vitro* diagnostic determination of total bilirubin in human serum and plasma based on a photometric test using 2,4-dichloroaniline (DCA) and detergents.

	ELITech Clinical Systems BILIRUBIN DIRECT 4+1 : ELITech Clinical Systems BILIRUBIN DIRECT 4+1 is intended for the quantitative *in vitro* diagnostic determination of direct bilirubin in human serum and plasma on ELITech Clinical Systems Selectra Pro Series Analyzers. It is not intended for use in Point of Care settings.	**ABX Pentra Bilirubin, Direct CP :** ABX Pentra Bilirubin, Direct CP reagent is intended for the quantitative *in vitro* diagnostic determination of direct bilirubin in human serum and plasma based on a photometric test using 2,4-dichloroaniline (DCA).
Indication for Use	Measurements of the levels of bilirubin (direct or total), an organic compound formed during the normal and abnormal distruction of red blood cells, are used in the diagnosis and treatment of liver, hemolytic hematological, and metabolic disorders, including hepatitis and gall bladder block. It is not intended for use in Point of Care settings.	Same
Sample Type	Serum, plasma	Same
Appearance of reagents	Liquid form, ready to use	Same

Differences

Parameter	New Device ELITech Clinical Systems BILIRUBIN TOTAL 4+1 & ELITech Clinical Systems BILIRUBIN DIRECT 4+1	Predicate Device ABX Pentra Bilirubin, Total CP & ABX Pentra Bilirubin, Direct CP K060325
Assay Format	**ELITech Clinical Systems BILIRUBIN TOTAL 4+1 :** R1: 8 x 20 mL R2: 8 x 5 mL **ELITech Clinical Systems BILIRUBIN DIRECT 4+1** : R1: 8 x 20 mL R2: 8 x 5 mL	**ABX Pentra Bilirubin, Total CP :** R1 : 29.5 mL R2 : 9.8 mL **ABX Pentra Bilirubin, Direct CP :** R1 : 24 mL R2 : 7 mL
Assay Technology	Malloy-Evelyn modified. End point.	Photometric test using 2,4-dichloroaniline (DCA), and a specific mixture of detergents.

Composition	**ELITech Clinical Systems BILIRUBIN TOTAL 4+1 :** Reagent 1: R1 Sulphanilic acid 29 mmol/L, Cetrimide 29 mmol/L. Reagent 2: R2 Sodium nitrite 11 mmol/L. **ELITech Clinical Systems BILIRUBIN DIRECT 4+1 :** Reagent 1: R1 Sulphanilic acid 29 mmol/L, Reagent 2: R2 Sodium nitrite 11 mmol/L.	**ABX Pentra Bilirubin, Total CP :** Reagent 1: Phosphate buffer : 50 mmol/L NaCl : 150 mmol/L Detergent, stabilizers Reagent 2: 2,4-Dichlorophenyl-diazonium salt : 5 mmol/L HCl : 130 mmol/L Detergent **ABX Pentra Bilirubin, Direct CP :** Reagent 1: EDTA-Na2 : 0.1 mmol/L NaCl : 150 mmol/L Sulfamic acid : 100 mmol/L Reagent 2: 2,4-Dichlorophenyl-diazonium salt : 0.5 mmol/L HCl : 900 mmol/L EDTA-Na2 : 0.13 mmol/L
Storage & Expiry	Store at 2-8°C and protect from light. Do not freeze. The reagents are stable until the expiry date stated on the label.	Reagents, in unopened cassettes, are stable up to the expiry date on the label if stored between 2-8°C. Do not freeze the reagents.
Assay Range	**ELITech Clinical Systems BILIRUBIN TOTAL 4+1 :** 0.25 mg/dL to 25.00 mg/dL (4.3 to 427.6 µmol/L) **ELITech Clinical Systems BILIRUBIN DIRECT 4+1 :** 0.08 mg/dL to 10.55 mg/dL (1.4 to 180.4 µmol/L)	**ABX Pentra Bilirubin, Total CP :** 2.4 to 450.0 µmol/L (0.14 to 26.3 mg/dL) **ABX Pentra Bilirubin, Direct CP :** 0.69 to 116 µmol/L (0.04 to 6.79 mg/dL)
Instrument	Selectra Series Analyzers	ABX Pentra 400

Reference Values	**ELITech Clinical Systems BILIRUBIN TOTAL 4+1 :** 0.2-1.2 mg/dL (3.4-21 µmol/L) **ELITech Clinical Systems BILIRUBIN DIRECT 4+1 :** < 0.2 mg/dL (3.4 µmol/L)	**ABX Pentra Bilirubin, Total CP :** Adults: 0.1 - 1.2 mg/dL (1.7 - 21 µmol/L) **ABX Pentra Bilirubin, Direct CP :** Adults and children: ≤ 0.2 mg/dL (≤ 3.4 µmol/L).
Controls	Recommended quality control material (not included): ELITech Clinical Systems ELITROL I (Normal control) (cleared in k110780) ELITech Clinical Systems ELITROL II (Pathologic control) (cleared in k110780)	Recommended quality control material (not included): ABX Pentra N Control & ABX Pentra P Control
Calibrator	Recommended calibration material (not included): ELITech Clinical Systems ELICAL 2 (cleared in k110780)	Recommended calibration material (not included): ABX Pentra Multical
Limit of Detection	**ELITech Clinical Systems BILIRUBIN TOTAL 4+1 :** 0.04 mg/dL (0.7 µmol/L) **ELITech Clinical Systems BILIRUBIN DIRECT 4+1 :** 0.01 mg/dL (0.2 µmol/L)	**ABX Pentra Bilirubin, Total CP :** 1.49 µmol/L (0.09 mg/dL). **ABX Pentra Bilirubin, Direct CP :** 0.69 µmol/L (0.04 mg/dL).

Interferences	**ELITech Clinical Systems BILIRUBIN TOTAL 4+1 :** Triglycerides: No significant interference up to 2100 mg/dL (23.73 mmol/L). Hemoglobin: No significant interference up to 500 mg/dL. Acetaminophen: No significant interference up to 30 mg/dL. Ascorbic acid: No significant interference up to 4 mg/dL. Acetylsalicylic acid: No significant interference up to 200 mg/dL. **ELITech Clinical Systems BILIRUBIN DIRECT 4+1 :** Triglycerides: No significant interference up to 2000 mg/dL (22.60 mmol/L) Hemoglobin: No significant interference up to 125 mg/dL. Acetaminophen: No significant interference up to 30 mg/dL. Ascorbic acid: No significant interference up to 0.5 mg/dL. Acetylsalicylic acid: No significant interference up to 200 mg/dL.	**ABX Pentra Bilirubin, Total CP :** Haemoglobin: No significant influence is observed up to 290 µmol/L (500 mg/dL). Triglycerides: No significant influence is observed up to 7 mmol/L (612.5 mg/dL). **ABX Pentra Bilirubin, Direct CP** : Haemoglobin: Do not use hemolysed samples. Triglycerides: No significant influence is observed up to an Intralipid® concentration (representative of lipemia) of 7 mmol/L (612.5 mg/dL).
On-board stability	28 days	ABX Pentra Bilirubin, Total CP : 25 days ABX Pentra Bilirubin, Direct CP : 30 days
Calibration frequency	Calibration frequency: 28 days Recalibrate when reagent lots change, when quality control results fall outside the established range, and after a maintenance operation.	The reagent is calibrated on Day 0. The calibration stability is checked by testing 2 control specimens. The calibration stability is 10 days. Note: A recalibration is recommended when reagent lots change, and when quality control results fall outside the range established.

9. **Test Principle:**

ELITech Clinical Systems BILIRUBIN TOTAL 4+1 :
Sulphanilic acid reacts with sodium nitrite to form diazotized sulphanilic acid.
In the presence of accelerator (cetrimide), conjugated and unconjugated bilirubin react with diazotized sulphanilic acid to form azobilirubin.
The increase of absorbance at 546 nm is proportional to bilirubin concentration.

ELITech Clinical Systems BILIRUBIN DIRECT 4+1 :
Sulphanilic acid reacts with sodium nitrite to form diazotized sulphanilic acid.
In the absence of accelerator, only conjugated bilirubin reacts with diazoted sulphanilic acid to form azobilirubin.
The increase of absorbance at 546 nm is proportional to bilirubin concentration.

10. **Performance Characteristics – Analytical Performance**

a. Precision/Reproducibility

Precision

Within-run and total precision results were obtained by performing two runs per day, two measures per run, for 3 concentrations of samples on 2 instruments during twenty operating days. The results are presented in the tables below:

For ELITech Clinical Systems BILIRUBIN TOTAL 4+1:

Level	n	Mean (mg/dL)	Precision %	
			Within-run CV%	Total CV%
Level 1	80	1.15	1.8	5.0
Level 2	80	4.08	0.4	3.1
Level 3	80	14.61	0.5	2.9

For ELITech Clinical Systems BILIRUBIN DIRECT 4+1:

Level	n	Mean (mg/dL)	Precision %	
			Within-run CV%	Total CV%
Level 1	80	0.36	3.8	5.2
Level 2	80	1.51	1.9	5.3
Level 3	80	3.99	0.9	4.7

b. Linearity/assay reportable range

The linearity of ELITech Clinical Systems BILIRUBIN TOTAL 4+1 was studied by mixing a sample with high value (25.13 mg/dL) and a sample with low value (0.25 mg/dL) to obtain 11 levels with equidistant concentrations and then measuring the Total Bilirubin concentration of each of the 11 levels using ELITech Clinical Systems BILIRUBIN TOTAL 4+1.
From this study, a measuring range from 0.25 – 25 mg/dL has been determined.
Auto-dilution 1 to 5 allows the use of the ELITech Clinical Systems BILIRUBIN TOTAL 4+1 with analyte concentration up to 60.00 mg/dL.

The linearity of ELITech Clinical Systems BILIRUBIN DIRECT 4+1 was studied by mixing a sample with high value (10.59 mg/dL) and a sample with low value (0.06 mg/dL) to obtain 11 levels with equidistant concentrations and then measuring the Direct Bilirubin concentration of each of the 11 levels using ELITech Clinical Systems BILIRUBIN DIRECT 4+1.
From this study, a measuring range from 0.08 – 10.55 mg/dL has been determined.
Auto-dilution 1 to 5 allows the use of the ELITech Clinical Systems BILIRUBIN DIRECT 4+1 with analyte concentration up to 50.00 mg/dL.

c. Detection limit

Limit of Detection:

ELITech Clinical Systems BILIRUBIN TOTAL 4+1 :
The limit of Detection was obtained from 15 measurements of 4 samples prepared from 4 patient samples measured using ELITech Clinical Systems BILIRUBIN TOTAL 4+1 and diluted with Albumin 6 g/dL - NaCl 0.9 % down to a concentration of circa 0.15 mg/dL.
The data are not Gaussian, so LoD= LoB + DS,β (where DS,β is determined by calculating the median minus the 5th percentile of the low activity sample distribution).
Limit of Detection : 0.04 mg/dL (0.7 µmol/L)

ELITech Clinical Systems BILIRUBIN DIRECT 4+1 :
The limit of Detection was obtained from 15 measurements of 4 samples prepared from 4 patient samples measured using ELITech Clinical Systems BILIRUBIN DIRECT 4+1 and diluted with Albumin 6 g/dL - NaCl 0.9 % to obtain a concentration of approximately 4 times the LoB.
The data are not Gaussian, so LoD= LoB + DS,β (where DS,β is determined by calculating the median minus the 5th percentile of the low activity sample distribution).
Limit of Detection : 0.01 mg/dL (0.2 µmol/L)

Limit of Quantification:

ELITech Clinical Systems BILIRUBIN TOTAL 4+1 :
The limit of Quantification was obtained from 15 measurements of 4 samples prepared from 4 patient samples measured using ELITech Clinical Systems BILIRUBIN TOTAL 4+1 reagent and diluted with Albumin 6 g/dL - NaCl 0.9 % down to a concentration circa 0.15 mg/dL.
Acceptance criteria: The acceptable Total Error for the determination Limit of Quantification is ≤ 0.07 mg/dL. The value must be equal or higher than the Limit of Detection.
Limit of Quantification = 0.15 mg/dL (2.6 µmol/L)

ELITech Clinical Systems BILIRUBIN DIRECT 4+1 :
The limit of Quantification was obtained from 15 measurements of 4 samples prepared from 4 patient samples measured using ELITech Clinical Systems BILIRUBIN DIRECT 4+1 reagent and diluted with Albumin 6 g/dL - NaCl 0.9 % down to a concentration circa of 0.08 mg/dL.
Acceptance criteria: The acceptable Total Error for the determination Limit of Quantification is ≤ 0.05 mg/dL. The value must be equal or higher than the Limit of Detection.
Limit of Quantification = 0.08 mg/dL (1.4 µmol/L)

d. Interference/analytical specificity

ELITech Clinical Systems BILIRUBIN TOTAL 4+1:

Interferences due to Triglycerides, Hemoglobin, Acetaminophen, Ascorbic acid, and Acetylsalicylic acid were investigated.

For each potential interferent tested, 2 serum sample pools at two Total Bilirubin levels were prepared:
-1st pool: low concentration at nominal 1.00 mg/dL
-2nd pool: high concentration at nominal 15.00 mg/dL
Aliquots of each of the serum sample pools were spiked with increasing interferent concentration. Test ranges covered at least the interferent level. Thus, there were two series of interferent spike for each potential interferent tested. A control sample was prepared from the sample pool diluted in the appropriate diluent.

Interferent	Test range	Number of different concentrations tested
Triglycerides	up to 3000 mg/dL	9
Hemoglobin	up to 500 mg/dL	9
Acetaminophen	up to 30 mg/dL	7
Ascorbic acid	up to 20 mg/dL	7
Acetylsalicylic acid	up to 200 mg/dL	7

Two (2) levels of control (ELITech Clinical Systems ELITROL I & II) were tested to check the calibration.
For both sample pools for each interferent, each point was measured in triplicate per run.
Acceptance criteria: an accepted bias of ±10% in sample pools with low (1.00 mg/dL) or high (15.00 mg/dL) nominal activity.

The results of testing interferences are the following:

- Triglycerides concentration up to 2100 mg/dL (23.73 mmol/L), Hemoglobin up to 500 mg/dL, Acetaminophen up to 30 mg/dL, Ascorbic acid up to 4 mg/dL. Acetylsalicylic acid up to 200 mg/dL.
- In very rare cases, monoclonal gammopathies (multiple myeloma), in particular IgM type (Waldenstrom's macroglobulinemia) can cause unreliable results.

The following statement will also be included in the labeling:

Many other substances and drugs may interfere. Some of them are listed in Young.
-Young, D. S., Effects of preanalytical variables on clinical laboratory tests, 2nd Ed., AACC Press, (1997).
-Young, D. S., Effects of drugs on clinical laboratory tests, 4th Ed., AACC Press, (1995).
-Berth, M. & Delanghe, J. *Protein precipitation as a possible important pitfall in the clinical chemistry analysis of blood samples containing monoclonal immunoglobulins: 2 case reports and a review of literature*, Acta Clin Belg., (2004), **59**, 263.

ELITech Clinical Systems DIRECT DIRECT 4+1:

Interferences due to Triglycerides, Hemoglobin, Acetaminophen, Ascorbic acid, and Acetylsalicylic acid were investigated.

For each potential interferent tested, 2 serum sample pools at two Direct Bilirubin levels were prepared:
-1st pool: low activity at nominal 0.40 mg/dL
-2nd pool: high activity at nominal 4.00 mg/dL

Aliquots of each of the serum sample pools were spiked with increasing interferent concentration. Test ranges covered at least the interferent level. Thus, there were two series of interferent spike for each potential interferent tested. A control sample was prepared from the sample pool diluted in the appropriate diluent.

Interferent	Test range	Number of different concentrations tested
Triglycerides	up to 3000 mg/dL	9
Hemoglobin	up to 500 mg/dL	9
Acetaminophen	up to 30 mg/dL	7
Ascorbic acid	up to 5 mg/dL	8
Acetylsalicylic acid	up to 200 mg/dL	7

Two (2) levels of control (ELITech Clinical Systems ELITROL I & II) were tested to check the calibration.

For both sample pools for each interferent, each point was measured in triplicate per run.

Acceptance criteria: an accepted bias of ±10% in sample pools with low (0.40 mg/dL) or high (4.00 mg/dL) nominal activity.

The results of testing interferences are the following:

- Triglycerides concentration up to 2000 mg/dL (22.60 mmol/L), Hemoglobin up to 125 mg/dL, Acetaminophen up to 30 mg/dL, Ascorbic acid up to 0.5 mg/dL, Acetylsalicylic acid up to 200 mg/dL.
- In very rare cases, monoclonal gammopathies (multiple myeloma), in particular IgM type (Waldenstrom's macroglobulinemia) can cause unreliable results.

The following statement will also be included in the labeling:

Many other substances and drugs may interfere. Some of them are listed in Young.
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-Berth, M. & Delanghe, J. *Protein precipitation as a possible important pitfall in the clinical chemistry analysis of blood samples containing monoclonal immunoglobulins: 2 case reports and a review of literature*, Acta Clin Belg., (2004), **59**, 263.

11. **Performance Characteristics – Comparison Studies**

a. Method comparison

Correlation studies were performed between ELITech Clinical Systems BILIRUBIN TOTAL 4+1 & ELITech Clinical Systems BILIRUBIN DIRECT 4+1 reagents on a Selectra ProM Analyzer.

ELITech Clinical Systems BILIRUBIN TOTAL 4+1 :
This study was performed using 100 serum patient samples from 0.32 to 23.02 mg/dL over a span of 5 days.
Regression analysis of the results yielded the following:
y = 0.948 x - 0.11 mg/dL.
r = 0.999
r^2 = 0.999
Standard error of the estimate Sy.x = 0.19 mg/dL.

ELITech Clinical Systems BILIRUBIN DIRECT 4+1 :
This study was performed using 100 serum patient samples from 0.09 to 10.52 mg/dL over a span of 5 days.
Regression analysis of the results yielded the following:
y = 0.926 x - 0.03 mg/dL.
r = 0.998
r^2 = 0.995
Standard error of the estimate Sy.x = 0.15 mg/dL.

b. Comparison study: Matrix comparison

ELITech Clinical Systems BILIRUBIN TOTAL 4+1 :
40 plasma patients (in lithium heparin samples, ranging from 0.33 to 24.08 mg/dL), were tested on ELITech Clinical Systems Selectra ProM Analyzer.
Regression analysis of the results yielded the following:
y = 0.985x + 0.03 mg/dL
r = 0.998
r^2 = 0.997
Standard error of the estimate Sy.x = 0.36 mg/dL

ELITech Clinical Systems BILIRUBIN DIRECT 4+1 :
40 plasma patients (in lithium heparin samples, ranging from 0.09 to 7.78 mg/dL), were tested on ELITech Clinical Systems Selectra ProM Analyzer.
Regression analysis of the results yielded the following:
y = 0.990x - 0.01 mg/dL
r = 0.999
r^2 = 0.997
Standard error of the estimate Sy.x = 0.14 mg/dL

c. Expected values/Reference Range
As indicated in the instructions for use for both ELITech Clinical Systems BILIRUBIN TOTAL 4+1 & ELITech Clinical Systems BILIRUBIN DIRECT 4+1, each laboratory should establish and maintain its own reference values. The values given are used as guidelines only.

ELITech Clinical Systems BILIRUBIN TOTAL 4+1 :

Adults : 0.2-1.2 mg/dL (3.4-21 µmol/L)

ELITech Clinical Systems BILIRUBIN DIRECT 4+1 :

< 0.2 mg/dL (3.4 µmol/L)

These reference values are from:

Wu, H.B., *General Clinical Tests*. Tietz Clinical guide to laboratory tests, 4th Ed., (W.B. Saunders eds. Philadelphia USA), (2006), 172

d. Clinical Studies:

Not applicable

e. Clinical Cut-off:

Not applicable

12. **Conclusion**

The information on the principle and performance of the devices contained in this premarket notification is complete and supports a decision that both ELITech Clinical Systems BILIRUBIN TOTAL 4+1 & ELITech Clinical Systems BILIRUBIN DIRECT 4+1 are substantially equivalent to their respective predicate device.