K111143

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510(k) Summary

SEP - 1 2011

Contact Person: Helen Landicho

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Summary prepared July 14, 2011

510(k) number:	K111143
Name of the device:	Poly-Chem® 90 Total Bilirubin
Device common name:	Total Bilirubin reagent/test system
Product code:	CIG
Regulation number:	862.1110
Classification:	Class II

Predicate Device:	Poly-Chem® Total Bilrubin
Device common name:	Total Bilirubin reagent/test system
510(k) number:	K973995
Manufacturer:	Randox Laboratories Ltd., 55 Diamond Road, Crumlin, Co. Antrim, United Kingdom, BT29 4QY
Product code:	CIG
Regulation number:	862.1110
Classification:	Class II

Device Description: Poly-Chem 90 Total Bilirubin is for the quantitative in vitro measurement of the level of total bilirubin in human serum on the Poly-Chem 90 clinical chemistry analyzer. The test methodology is a colorimetric method based on that described by Jendrassik and Grof (1938). Total bilirubin is determined in the presence of caffeine, which releases albumin bound bilirubin, by the reaction with diazotized sulphanilic acid.

Intended use: Poly-Chem 90 Total Bilirubin is for the quantitative in vitro measurement of the level of total bilirubin in human serum on the Poly-Chem 90 clinical chemistry analyzer. Measurements of the level

of bilirubin, an organic compound formed during the normal and abnormal destruction of red blood cells, are used in the diagnosis and treatment of liver, hemolytic hematological, and metabolic disorders, including hepatitis and gall bladder block.

Similarities and Differences with Predicate Device

Similarities and Differences Total Bilirubin		
Item	Poly-Chem 90 Total Bilirubin	Poly-Chem Total Bilirubin
Intended Use	For the quantitative in vitro measurement of the level of total bilirubin in human serum on the Poly-Chem 90 analyzer.	For the quantitative in vitro measurement of the level of total bilirubin in human serum and plasma on the Poly-Chem analyzer.
Indications for Use	Measurements of the level of bilirubin, an organic compound formed during the normal and abnormal destruction of red blood cells, are used in the diagnosis and treatment of liver, hemolytic hematological, and metabolic disorders, including hepatitis and gall bladder block.	Same
Sample type	Serum	Serum and plasma
Test methodology	Colorimetric	Same
Precision	Intraassay: %CV from 0.4% to 1.7% Interassay: %CV from 4.3% to 5.4% Samples from 0.50 to 25.71 g/dL	Intraassay: %CV from 2.1% to 2.3% Interassay: %CV from 1.4% to 1.9% Samples from 0.92 to 5.29 mg/dL
Measuring range	0.1– 27.5 mg/dL	0.09 - 25 mg/dL
Comparison with Predicate	y = 0.98x – 0.03, r = 0.9998; 82 samples from 0.10 – 24.10 mg/dL	y = 0.93x + 0.02, r = 0.98; 33 samples from 0.09 – 4.86 mg/dL
Storage	15 - 25°C	Same
Stability	Same	Same
Expected values	Adults: up to 1 mg/dl (17 µmol/l)	Same
Reagent Kit	Same	Same
Analyzer	Poly-Chem 90	Poly-Chem 180

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Summary of performance testing

To demonstrate substantial equivalence, performance characteristics that were tested included precision, linearity, sensitivity, interferences, and method comparison. Results of this testing are summarized below. The results indicate that Poly-Chem 90 Total Bilirubin is substantially equivalent to currently marketed Total Bilirubin reagent test systems.

Precision

			Within run		Between run	
Sample	Instrument	Mean	SD	CV	SD	CV
1	1	0.50	0.008	1.65	0.027	5.40
	2	0.50	0.006	1.19	0.025	5.10
2	1	5.02	0.021	0.42	0.215	4.29
	2	4.98	0.032	0.65	0.225	4.51
3	1	25.71	0.059	0.23	1.270	4.94
	2	25.42	0.249	0.98	1.336	5.26

Linearity of the test

0.07 – 27.5 mg/dL

Sensitivity

Limit of Blank	Limit of Detection	Limit of Quantitation (10% CV)
0.0043 mg/dL	0.0184 mg/dL	0.08 mg/dL

Interference

Highest level tested with no interference:

Hemoglobin 600 mg/dL

Triglyceride 554 mg/dL

Comparison with predicate device

n	Range of samples	Slope (95% CI)	Intercept (95% CI)	r
82	0.10 – 24.10	0.98 (0.98 to 0.99)	-0.03 (-0.04 to -0.01)	0.9998

Conclusions

Poly-Chem 90 Total Bilirubin is substantially equivalent to currently marketed Total Bilirubin reagent test systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Polymedco, Inc
c/o Helen Landicho, RAC
Vice President, Regulatory Affairs
510 Furnace Dock Rd
Cortlandt Manor , New York, 10567

SEP 0 1 2011

Re: K111143

Trade name:	Poly-Chem® 90 Total Bilirubin
Regulation Number:	21CFR §862.1110
Regulation Name:	Total Bilirubin test system
Regulatory Class:	Class II
Product Codes:	CIG
Dated:	August 18, 2011
Received:	August 22, 2011

Dear Ms. Landicho,

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Indications for Use

510(k) Number (if known):

Device Name: Poly-Chem 90 Total Bilirubin test

Indications For Use:

Poly-Chem 90 Total Bilirubin is for the quantitative in vitro measurement of the level of total bilirubin in human serum on the Poly-Chem 90 clinical chemistry analyzer. Measurements of the level of bilirubin, an organic compound formed during the normal and abnormal destruction of red blood cells, is used in the diagnosis and treatment of liver, hemolytic hematological, and metabolic disorders, including hepatitis and gall bladder block.

Prescription Use ___√___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

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