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

May 10, 2017

ROCHE DIAGNOSTICS OPERATIONS (RDO)
PATRICK STIMART
REGULATORY AFFAIRS CONSULTANT
9115 HAGUE ROAD
INDIANAPOLIS IN 46250

Re: K171080
Trade/Device Name: ALP IFCC Gen.2
Regulation Number: 21 CFR 862.1050
Regulation Name: Alkaline phosphatase or isoenzymes test system
Regulatory Class: II
Product Code: CJE
Dated: April 10, 2017
Received: April 11, 2017

Dear Patrick Stimart:

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)*

k171080

Device Name
ALP IFCC Gen.2

Indications for Use *(Describe)*

ALP IFCC Gen.2 is an in vitro test intended for the quantitative determination of the catalytic activity of alkaline phosphatase in human serum and plasma on COBAS INTEGRA systems. Measurements of alkaline phosphatase or its isoenzymes are used in the diagnosis and treatment of liver, bone, parathyroid, and intestinal diseases.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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ALP IFCC Gen.2
510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

In accordance with 21 CFR 807.87, Roche Diagnostics hereby submits official notification as required by Section 510(k) of the Federal Food, Drug and Cosmetics Act of our intention to market the device described in this Premarket Notification Special 510(k).

The purpose of this Special 510(k) Premarket Notification is to inform FDA of the proposed modifications to the ALP IFCC Gen.2 labeling and provide sufficient detail to support a determination of substantial equivalence. The primary change is the change in traceability from the IFCC method per Tietz , Rinker, Shaw. J Clin Chem Clin Biochem 1983;21:731-748, to the revised IFFC version per Schumann, Klauke, Canalias, et al. Clin Chem Lab Med 2011 Sep;49(9):1439-46.

Other changes which are deemed by Roche not to require premarket notification will also be described.

Note: There were no prior submissions for this device for which FDA provided feedback related to the data or information needed to support substantial equivalence.

Submitter Name	Roche Diagnostics
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Contact	Primary: Patrick Stimart Phone (317) 521-3954 FAX (317) 521-2324 Email: patrick.stimart@roche.com Secondary: Miranda Deverall Phone (317) 521-2897 FAX (317) 521-2324 Email: miranda.deverall@roche.com
Date Prepared	March 31, 2017
Proprietary Name	ALP IFCC Gen.2
Common Name	ALP2
Classification Name	Alkaline phosphatase or isoenzymes test system(21CFR862.1050, Class 2 device)
Product Codes	CJE
Predicate Devices	The candidate device is a modification of the predicate device. The device name, ALP IFCC Gen.2, is unchanged from how it was cleared in 510(k) K033185.
Establishment Registration	For the ALP IFCC Gen.2, the establishment registration number for Roche Diagnostics GmbH in Mannheim, Germany is 9610126, and for Penzberg, Germany, 9610529. The establishment registration number for Roche Diagnostics in the United States is 1823260.

1. DEVICE DESCRIPTION

The Roche ALP IFCC Gen.2 assay provides quantitative measurement of the catalytic activity of alkaline phosphatase in human serum and plasma in accordance with a standardized method.. The reagents are packaged in a cassette with two bottles labeled with their instrument positioning, R1 (position B) and SR (position C).

In the presence of magnesium and zinc ions, p-nitrophenyl phosphate is cleaved by phosphatases into phosphate and p-nitrophenol. The p-nitrophenol released is directly proportional to the catalytic ALP activity. It is determined by measuring the increase in absorbance.

Note: Since ALP IFCC Gen.2 is a reagent, drawings, schematics, illustrations, photos and figures are not pertinent to describe the device and therefore are not present in this submission.

2. INDICATIONS FOR USE

ALP IFCC Gen.2 is an in vitro test intended for the quantitative determination of the catalytic activity of alkaline phosphatase in human serum and plasma on COBAS INTEGRA systems. Measurements of alkaline phosphatase or its isoenzymes are used in the diagnosis and treatment of liver, bone, parathyroid, and intestinal diseases.

Note: The intended use of the modified device, as described in its labeling, has not changed as a result of the modification.

3. TECHNOLOGICAL CHARACTERISTICS

The candidate device, ALP IFCC Gen.2 (ALP2), has been modified from the predicated device with the following changes and additions as described in the candidate assay method sheet.

- The traceability of the ALP2 assay was changed from IFCC (1983) reference method to the modified IFCC (2011) reference method, which is noted in the Calibration section of the method sheet.
- I index and L index levels for the icterus and lipemia interference claims were added to the Limitations – interference section of the method sheet.

The following tables compare the ALP IFCC Gen.2 with its predicate device, ALP IFCC Gen.2 (k033185).

Table 1 Assay Comparison, General Assay Features

Feature	Predicate Device ALP IFCC Gen.2 (K033185)	Candidate Device ALP IFCC Gen.2
Intended use / Indications for use	In vitro test for the quantitative determination of the catalytic activity of alkaline phosphatase (EC 3.1.3.1; ortho-phosphoric monoester phosphohydrolase, alkaline optimum) in serum and plasma on COBAS INTEGRA systems.	Same
Test principle	Colorimetric assay in accordance with a standardized method. In the presence of magnesium and zinc ions, p-nitrophenyl phosphate is cleaved by phosphatases into phosphate and p-nitrophenol. The p-nitrophenol released is directly proportional to the catalytic ALP activity. It is determined by measuring the increase in absorbance at 409 nm.	Same
Instrument	COBAS INTEGRA 400/700/800	COBAS INTEGRA 400 plus
Sample type	Serum, and Heparin (Li-, Na-, NH_4) plasma	same
Calibrator	Calibrator for automated systems (C.f.a.s.)	same
Controls	Precinorm U, Precinorm U plus, Precipath U, Precipath U plus	Precinorm U, Precinorm U plus, PreciControl ClinChem Multi 1 Precipath U, Precipath U plus, PreicControl ClinChem Multi 2

Feature	Predicate Device ALP IFCC Gen.2 (K033185)	Candidate Device ALP IFCC Gen.2
Traceability/Standardization	This method has been standardized manually against the original IFCC formulation. (Lit. ref. Tietz 1983)	This method has been standardized against the IFCC procedure. (Lit. ref. Schumann 2011)
Reagent stability	Shelf life at 2-8°C: See expiration date on cassette On-board in use at 10 to 15°C: 4 weeks	same

Table 2: Assay Comparison, Labeled Performance Characteristics

Feature	Predicate Device ALP IFCC Gen.2 (K033185)	Candidate Device ALP IFCC Gen.2
Measuring Range	0- 1200 U/L	3.0- 1200 U/L
Precision	See predicate method sheet	Same
Lower Detection Limit (LDL)	2 U/L	3.0 U/L
Method Comparison	See predicate method sheet	Same
Limitations - interference	Hemolysis: No significant interference up to hemoglobin level of 0.16 mmol/L (2.5 g/L). Icterus: No significant interference. Lipemia: No significant interference.	Hemolysis: Same Icterus: No significant interference up to an I index of 42 for conjugated bilirubin and 60 for unconjugated bilirubin Lipemia: No significant interference up to an L index of 2000.
Expected values	See predicate method sheet	See candidate method sheet. Expected values updated to a more recent literature reference.

4. NON-CLINICAL PERFORMANCE EVALUATION

Based on the risk analysis, the modifications to the ALP IFCC Gen.2 could include potential risks due to the following:

(i) Added specific interference levels for icterus and lipemia, which could cause false ALP values being reported.

(ii) Traceability change for the ALP2 assay could result in inaccurate patient results and the imprecision of the assay.

Verification, validation and testing activities were conducted to establish the performance, which included recovery in controls, linearity, method comparison, within run precision and interference characteristics of the modified device. The device passed all of the tests based on pre-determined Pass/Fail criteria.

5. CONCLUSIONS

The submitted information in this premarket notification supports a substantial equivalence decision. The differences between predicated and candidate do not impact the indications for use or technological characteristics.