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

ROCHE DIAGNOSTICS
EDIE BRUNT
PRINCIPAL, REGULATORY AFFAIRS
9115 HAGUE ROAD
INDIANAPOLIS IN 46250

April 4, 2017

Re: K170678
Trade/Device Name: ß-CrossLaps CalCheck 5
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: I, Reserved
Product Code: JJX
Dated: March 3, 2017
Received: March 6, 2017

Dear Edie Brunt:

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)*
k170678

Device Name
ß-CrossLaps CalCheck 5

Indications for Use *(Describe)*
This CalCheck set is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys ß-CrossLaps/serum reagent on the cobas e immunoassay analyzers.

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.

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ß-CrossLaps CalCheck 5
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 510(k).

The purpose of this Traditional 510(k) Premarket Notification is to obtain FDA review and clearance for the ß-CrossLaps CalCheck 5.

Submitter Name	Roche Diagnostics
Address	9115 Hague Road P.O. Box 50416 Indianapolis, IN 46250-0457
Contact	Edie Brunt Phone: (317) 521-4668 FAX: (317) 521-2324 Email: edie.brunt@roche.com
Date Prepared	March 3, 2017
Proprietary Name	ß-CrossLaps CalCheck 5
Common Name	Beta-CrossLaps CalCheck 5
Classification Name	Single (Specified) Analyte Controls (Assayed and Unassayed))
Product Codes, Regulation Numbers	JJX, 862.1660
Predicate Devices	CalCheck Vitamin D Total II
Establishment Registration	For the ß-CrossLaps CalCheck 5, 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 ß-CrossLaps CalCheck 5 is used for the calibration verification and the assessment of the measuring range as needed by the laboratory certification agencies such as College of American Pathologists or CLIA certification. The CalChecks are a customer convenience product and not required to assess the performance.

2. INDICATIONS FOR USE

This CalCheck set is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys ß-CrossLaps/serum reagent on the **cobas e** immunoassay analyzers.

3. TECHNOLOGICAL CHARACTERISTICS

The following table compares the ß-CrossLaps CalCheck 5 with its predicate device, CalCheck Vitamin D Total II (k162840).

Table 1: CalCheck Comparison

Feature	CalCheck Vitamin D Total II	ß-CrossLaps CalCheck 5
Intended Use/Indications for Use	This CalCheck set is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys Vitamin D total II reagent on the **cobas e 411** immunoassay analyzer.	This CalCheck set is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys ß-CrossLaps/serum reagent on the **cobas e** immunoassay analyzers.
Analyte	25-hydroxyvitamin D_3	Synthetic β-CTx peptide in a CrossLaps free human serum matrix
Matrix	Human serum	Same
Levels	Five	Same

Feature	CalCheck Vitamin D Total II	ß-CrossLaps CalCheck 5
Target Ranges	Approximate target concentrations: Check 1: ≤ 5 ng/mL Check 2: 17.5 – 22.4 ng/mL Check 3: 46.5 - 54.4 ng/mL Check 4: 75.5 – 84.4 ng/mL Check 5: 94.5 – > 100 ng/mL	Approximate target concentrations: Check 1: ≤ 0.05 ng/mL Check 2: 0.4 – 0.6 ng/mL Check 3: 2.7 – 3.3 ng/mL Check 4: 4.0 – 5.0 ng/mL Check 5: 5.4 – >6.0 ng/mL
Format	Lyophilized	Same
Handling	Reconstitute the contents of each CalCheck vial with exactly 1.0 mL distilled or deionized water. Allow the bottles to stand closed for 15 minutes. Mix gently by inversion to ensure homogeneity.	Same
Storage and Stability	Reconstituted control serum: At 20-25°C – 4 hours	Same

4. NON-CLINICAL PERFORMANCE EVALUATION

The ß-CrossLaps CalCheck 5 matrix, human serum, is identical to the Master Calibrators (human serum sample panel) used for the Elecsys ß-CrossLaps/serum assay.

ß-CrossLaps CalCheck 5 was evaluated for value assignment and stability.

4.1. Value Assignment

For each ß-CrossLaps CalCheck 5 lot manufactured, the CalChecks are run in duplicate on at least two (2) modules (each with two measuring cells) of the **cobas e** 801 with at least two runs. The assigned value of each CalCheck is defined as the median value obtained over at least six (6) determinations (runs) of the respective CalCheck.

The CalCheck assigned range is calculated as ± 27% of the assigned value for levels 2 through 5. The label states that each laboratory should establish appropriate acceptance criteria when using this product for its intended use.

Target Values

β-CrossLaps CalCheck 5 Level	Target Value [ng/mL]
Check 1	≤ 0.05
Check 2	0.5
Check 3	3.0
Check 4	4.5
Check 5	6.0

4.2. Stability

The following studies were performed in order to verify the stability claims for the ß-CrossLaps CalCheck 5:

Study 1: Open vial stability

Study 2: Accelerated stability

Study 3: Real-time stability

4.2.1. Open Vial Stability

The on-test and reference materials were tested in duplicate. The on-test material was reconstituted and stored for 4 hours at 25ºC (in an open vial). The reference material was a freshly reconstituted set of CalChecks. The on-test recovery was calculated as a percent of the reference value. The acceptance criterion for CalCheck Level 1 was ≤ 0.05 ng/mL and for CalCheck Levels 2 -5 was 90-110% recovery of the reference material value. The data supports the method sheet claim that reconstituted β-CrossLaps CalCheck 5 is stable for 4 hours at 20-25°C.

The CalCheck products are not stored on-board the analyzer, therefore no on-board stability claim is made.

4.2.2. Accelerated Stability

The on-test material was stored lyophilized (as supplied to the user) at 35°C for 3 weeks. The reference material was a freshly reconstituted set of CalChecks (stored at 2-8°C). After 3 weeks, the test and reference materials were tested in duplicate. The on-test recovery was calculated as a percent of the reference value. The acceptance criterion for CalCheck Level 1 was ≤ 0.05 ng/mL

and for CalCheck Levels 2 -5 was 90-110% recovery of the reference material value. The accelerated stability model employed supports an initial shelf life claim of 18 months when the β-CrossLaps CalCheck 5 are stored under normal storage conditions of 2-8°C.

4.2.3. Real-time (Shelf-life) Stability

In the on-going real-time stability study, the ß-CrossLaps CalCheck 5 test material is stored at 2-8°C. The CalChecks are tested at T=0 and at specified intervals over the shelf life of the device up to the planned shelf life plus one month. For the lot on stability, data for the time-points at 0, 7, 13 and 19 months tested in duplicate will be available. The average on-test recovery value will be calculated as percent recovery compared to the unstressed reference value (stored at -20°C). The acceptance criterion for CalCheck Level 1 was ≤ 0.05 ng/mL and for CalCheck Levels 2 -5 was 90-110% recovery of the reference material value. Currently the shelf-life claim is 18 months.

Conclusions

The information provided in this 510(k) Premarket Notification will support a determination of substantial equivalence for the ß-CrossLaps CalCheck 5. The data supports a safe, effective device which performs as well as or better than the predicate device.