April 19, 2018

Roche Diagnostics
Bin Sun
Regulatory Affairs Principal
9115 Hague Road
Indianapolis, Indiana 46250

Re: K180684
Trade/Device Name: CoaguChek XS Plus System
Regulation Number: 21 CFR 864.7750
Regulation Name: Prothrombin time test
Regulatory Class: Class II
Product Code: GJS
Dated: March 14, 2018
Received: March 15, 2018

Dear Bin Sun:

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 Part 801 and Part 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Leonthena R. Carrington -S

Lea Carrington
Director
Division of Immunology
and Hematology 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180684

Device Name
CoaguChek® XS Plus System

Indications for Use *(Describe)*

The CoaguChek XS Plus system is intended for use by professional healthcare providers for quantitative prothrombin time testing for the monitoring of warfarin therapy. The system uses fresh capillary or non-anticoagulated venous whole blood.

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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CoaguChek XS Plus Super Sani Cloth claims extension

Special 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 Special 510(k) Premarket Notification is to obtain FDA review and clearance for the CoaguChek XS Plus Super Sani Cloth claims extension. The CoaguChek XS Plus System labeling will be modified to add a new cleaning and disinfecting product for use with our device, Super Sani-Cloth® (EPA #9480-4).

The CoaguChek XS Plus System is a prothrombin time test system, a Class II medical device according to 21 CFR 864.7750. Super Sani-Cloth is a General Purpose Disinfectant, a Class I exempt product, according to 21 CFR 880.6890.

The CoaguChek XS Plus System has not changed since its clearance on K071041. No technological, material, performance, or design changes to the CoaguChek XS Plus System have been implemented since its clearance on K071041. This submission pertains only to the performance of Super Sani- Cloth wipes for the effective cleaning and disinfecting of the CoaguChek XS Plus System housing and components.

Please note that we intend to add the Super Sani-Cloth to the CoaguChek XS Plus System product labeling for cleaning and disinfection purposes. Previously, 70% ethanol or isopropyl alcohol and 10% sodium hypochlorite solution were cleared as recommended cleaning/disinfecting solutions. The Super Sani-Cloth will replace the sodium hypochlorite solutions in the product labeling.

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Date Prepared	March 9, 2018
Proprietary Name	CoaguChek XS Plus System
Common Name	Test, Time, Prothrombin
Classification Name	Prothrombin time test
Product Codes, **Regulation Numbers**	GJS, Class II, 21 CFR 864.7750
Predicate Devices	The 510(k) history for the CoaguChek XS Plus System is K071041, cleared on May 11, 2007. Please note that in this submission we did not make any changes or enhancements to the CoaguChek XS Plus system.
Establishment Registration	For the CoaguChek XS Plus System, the establishment registration number for Roche Diagnostics GmbH in Mannheim, Germany is 9610126.

1. DEVICE DESCRIPTION

No technological, material, performance, or design changes to the CoaguChek XS Plus System have been implemented since its clearance on K071041.

Thus, the device description for the CoaguChek XS Plus System remains the same as that presented and cleared in K071041.

This submission deals only with the performance of Super Sani-Cloth wipes for the effective cleaning and disinfection of the CoaguChek XS Plus System housing and components.

Please note that we intend to modify the CoaguChek XS Plus System labeling by adding the Super Sani-Cloth for cleaning and disinfection of the system. Previously, 70% ethanol or isopropyl alcohol and 10% sodium hypochlorite solution were cleared as recommended cleaning/disinfecting solutions. The Super Sani-Cloth will replace the sodium hypochlorite solutions in the product labeling.

2. INDICATIONS FOR USE

The use of Super-Sani Cloth wipes for the cleaning and disinfection of the CoaguChek XS Plus System is the focus of this Special 510(k) and does not change the Intended Use or Indications for Use of the system.

Therefore, the Intended Use and Indications for Use for the CoaguChek XS Plus System remains the same as the cleared CoaguChek XS Plus System (K071041).

The CoaguChek XS Plus system is intended for use by professional healthcare providers for quantitative prothrombin time testing for the monitoring of warfarin therapy. The system uses fresh capillary or non-anticoagulated venous whole blood.

3. TECHNOLOGICAL CHARACTERISTICS

The fundamental scientific technology of the CoaguChek XS Plus System (K071041) has not changed.

4. ACCESSORY NAME (SUPER SANI-CLOTH)

Proprietary name: Super Sani-Cloth (manufactured by PDI)

Classification names: Disinfectant, Medical Devices

Subsequent Product Code: LRJ, General Purpose Disinfectant

510(k) History: n/a, Class I exempt

5. INSTRUMENT CLEANING AND DISINFECTION ROBUSTNESS STUDY

No technological, material, performance, or design changes to the CoaguChek XS Plus System have been implemented since its clearance on K071041.

The corresponding test results on the device components demonstrate that the Super Sani-Cloth wipes are effective for the cleaning and disinfection of the device.

Robustness and effectiveness cleaning and disinfecting testing on the CoaguChek XS Plus System for Super Sani-Cloths demonstrated that the device meets the performance requirements for its intended use. Acceptance criteria were met when testing with venous blood the CoaguChek XS Plus meters that had been subjected to 10,950 C&D cycles representing three-years lifetime of the meter based on a testing frequency of 10 tests per day. Neither meter accuracy nor meter functionality were impacted by the cleaning and disinfection procedure.

Overall, the data demonstrate that the CoaguChek XS Plus System operates in the same manner when cleaning and disinfecting occurs with the Super Sani-Cloth wipes.

Please note that we intend to modify the CoaguChek XS Plus System labeling by adding the Super Sani-Cloth for cleaning and disinfection of the system. Previously, 70% ethanol or isopropyl alcohol and 10% sodium hypochlorite solution were cleared as recommended cleaning/disinfecting solutions. The Super Sani-Cloth will replace the sodium hypochlorite solutions in the product labeling.

6. UPDATED LABELING

The CoaguChek XS Plus Operator's Manual has been updated to reflect Super Sani-Cloth. This is included in Section 10. The Maintenance & Care topic starts on page 121.