



## SPECIAL 510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION DECISION SUMMARY

### I Background Information:

#### A 510(k) Number

K253188

#### B Applicant

Roche Diagnostics

#### C Proprietary and Established Names

CoaguChek XS Plus System

#### D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
GJS	Class II	21 CFR 864.7750	81 Hematology

### II Review Summary:

This 510(k) submission contains information/data on modifications made to the submitter's own CLASS II device requiring 510(k). The following items are present and acceptable.

1. The name and 510(k) number of the SUBMITTER'S previously cleared device.
2. Submitter's statement that the **INDICATIONS FOR USE/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials (labeling changes are permitted as long as they do not affect the intended use).
3. A description of the device **MODIFICATION(S)**, including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed. This change was for:**
  - **Added barcode scanner built into the meter housing.**

- **Added routine maintenance cleaning process with water and cleaning of the clear plastic barcode window with a dry cloth.**
  - **Added temperature sensor below the test strip guide to detect a heater malfunction and Heater Self Check 2 (HSC2) failsafe error implemented in the software.**
  - **A modified printed circuit board (PCB) due to the addition of a barcode scanner and component obsolescence. The PCB changed from a barrel connector to a USB C connector for AC power adapter charging capability only. No data transfer is possible via the USB C connector.**
  - **Added rechargeable battery pack to replace the four standard type AA alkaline non-rechargeable batteries with a new dimensional footprint installed in the meter. The meter can also be powered by the AC power adapter provided via the USB C connector with the rechargeable battery installed.**
  - **Added hardware and software for the use of a barcode scanner.**
4. Comparison Information (i.e., similarities and differences) to the submitter's legally marketed predicate device including, labeling, intended use, and physical characteristics.
  5. A Design Control Activities Summary which includes:
    - a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.
    - b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied.

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared device.