SPECIAL 510(K): DEVICE MODIFICATION
OIR DECISION MEMORANDUM

510(k) Number: K180684

This 510(k) submission contains information/data on modifications made to the applicant's own class II or class I devices requiring 510(k). The following items are present and acceptable:

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1. The name and 510(k) number of the applicant's previously cleared device: CoaguChek XS Plus System, K071041.

2. Applicant's statement that the **INDICATION/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.

3. A description of the device **MODIFICATION,** 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 new cleaning and disinfection instructions in the labeling to include Super Sani-Cloth Germicidal Disposable Wipes.

4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, target population, material, technology, performance, and design changes.
5. A **Design Control Activities Summary** which includes:
   a) Identification of Risk Analysis method 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.

      Sponsor followed ISO 14971 Second edition (Medical devices - Application of risk management to medical devices) to evaluate risk specific to cleaning and disinfection of the CoaguChek XS Plus System. The scope of the risk analysis covers disinfectant seeping into the device which may affect heater of the device, battery contact, temperature sensors and strip sensors. It was concluded that the proposed change does not pose any additional risks and there is no impact on the safety or effectiveness of the product.

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 applicant's description of the modifications and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The applicant 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 (or their pre-amendment) device.