

SPECIAL 510(k): Device Modification ODE Review Memorandum

To: THE FILE

RE: DOCUMENT NUMBER K034013 "Special"

REAADS Anti-DsDNA Quantitative Test Kit

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable:

1. **REAADS Anti-DsDNA Quantitative Test Kit previously cleared K893896.**
2. Submitter'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(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**.
The changes include:
 - **Traceability of WHO standard with results reported in IU/mL units, including cutoff and upper detection in IU/mL,**
 - **Increased reagent fill volumes to accommodate use on automated instrument platforms,**
 - **Change from two component to one component substrate (TMB/H₂O₂)**
 - **Reduce strength of stopping solution from 2.5N to 0.36N sulfuric acid for safety reasons.**
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and performance characteristics which include the following:
 - A value assignment of the calibrator was determined by serially diluting the WHO standard to form a multi-point curve. Internal value assignment reference panels and calibrators are interpolated from the WHO standard through linear regression calculations.
 - Cutoff determination for the WHO standard units (IU/mL) was determined to be 117 IU/mL. The previously established cutoff of 26 AU/mL remains.
 - Specificity and Sensitivity studies and agreement between the two measurement units.
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
 - c) A declaration of conformity with design controls. The declaration of conformity should include:
 - i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and
 - ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.
6. A **Truthful and Accurate Statement, a 510(k) Summary or Statement and the Indications for Use Enclosure (and Class III Summary for Class III devices).**

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 (or their preamendment) device.

Comments:

The sponsor stated that the modification also includes the correction to the labeling to reflect product clearance on the predicate device as Quantitative instead of Semi-quantitative. However, it was noted that the predicate device was already cleared to be a quantitative assay. An email memo is enclosed to clarify the confusion which states that *"The product was originally cleared in 1989 as a Quantitative Assay for the Determination of IgG and IgM anti-dsDNA. Around 1993, the name was inadvertently changed to state semi-quantitative. All products at that time in our company were semi-quantitative and the initiator of the change concluded that this product must also be semi-quantitative and initiated the change in name."*

This does not affect the substantial equivalence determination of the device.