SPECIAL 510(k): Device Modification
OIR Decision Memorandum

To: THE FILE RE: DOCUMENT NUMBER K151867

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. The name and 510(k) number of the SUBMITTER'S previously cleared device: STA-R Evolution® Expert Series Hemostasis System, K093001.

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 **MODIFICATIONS,** 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 the following modifications: (1) new device name (STA R Max®), (2) implementation of a new graphical user interface (GUI) to use the graphical chart of Max line of STA Analyzers, (3) changes to the external design (color and shape) of the analyzer which include modifications of the openings and the addition of a new computer table for improved ergonomics, (4) improvement of the communication protocol with a Laboratory Information System (LIS) or a middleware so more information can be exchanged. (Attachment 9)

4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, target population, anatomical sites, point of use, electrical safety, chronometric and photometric method of coagulation detection, barcode ID of samples and reagents, and disposables are similar. Differences include dimensions, integrated PC microprocessor, memory and hard disk, weight, connections, computer table, and touch screen. (Attachment 9)

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 utilizing the FMEA model in compliance with ISO 14971:2007. (p 27-29/44 and Attachment 11)
   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. (Attachment 18)
   c) 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 and the results demonstrated that the predetermined acceptance criteria were met. (Attachment 10)
      ii) A statement signed by the individual responsible, the manufacturing facility is in conformance with the design control procedure requirement specified in 21 CFR 820.30 and the records are available for review. (Attachment 10).

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 modifications 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.