SPECIAL 510(k): Device Modification
OIR Decision Summary

To: THE FILE RE: DOCUMENT NUMBER K160502

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: TEG® 6s Hemostasis System; K140893 and K150041.
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**.

   This change was for the TEG manager 2.0.0, an optional accessory to Haemonetics TEG 6s Hemostasis System. TEG Manager 2.0.0 is an application that provides remote viewing of current and historical patient tracing and test results created by the TEG 6s analyzers, and administration of all connected TEG 6s devices. TEG Manager interfaces with the TEG analyzers to obtain clinical data and retrieves patient information from external Hospital Information System (HIS). Users cannot manipulate the data that is stored and displayed within TEG Manager or input any additional clinical data in the software.
4. **Comparison Information** (similarities and differences) to the applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, operating principle, hardware and test parameters.
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.

      Risk Analysis methods comprise the Device Hazard Analysis (HAs); Risk Management Plan and Report to include Initial Risk Assessment, Residual Risk Level Interpretation and Risk Management Activities as well as Verification and Validation Documentation.

   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 risk analyses for the TEG Manager were conducted in accordance with ISO 14971: 2007, The analyses concluded that the controls and mitigations are effective at reducing the likelihood of the hazard causes. All remaining risks associated with the identified hazards have been evaluated and deemed to be within acceptable levels in regards to the intended application and use of the device to ensure safety and effectiveness according to the Quality System. Cybersecurity has been included in the risk analysis. 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 the 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 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.