SPECIAL 510(k): Device Modification
ODE Review Memorandum (Decision Making Document is Attached)

To: THE FILE **RE:** DOCUMENT NUMBER
K033277

HYDRAGEL 3 CSF ISOFOCUSING and HYDRAGEL 6 CSF ISOFOCUSING

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 (delete/add items as necessary):

1. HYDRAGEL 3 CSF and HYDRAGEL 6 CSF (k981048)
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 were *1) isoelectric focusing replaces zonal electrophoresis for protein separation, 2) chemical compositions of the agarose gels and electrophoretic buffer, 3) voltage, 4) requires 2 mg/dL instead of 1 mg/dL total IgG for analysis, 5) detects IgG oligoclonal bands and not IgG, IgA and IgM and 6) for the HYDRAGEL 9 CSF ISOFOCUSING kit, the agarose gel has 18 tracks instead of 12 tracks.*
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, *labeling, intended use, indication for use, methodology, kit component specification, packaging and analytical performance*.
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 – *Fault Tree analysis (see pg. 3)*
   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 (*see pgs. 3, 4, 6 and 8*)
   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 (*see pg. 18)*, 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 (*see pg. 19)*.
6. A **Truthful and Accurate Statement**, a **510(k) Statement** and the **Indications for Use Enclosure.**

The labeling for these modified subject devices have been reviewed to verify that the indication/intended uses for these devices are unaffected by the modifications. In addition, the submitter's description of these 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 these devices be determined substantially equivalent to the previously cleared devices.

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(Reviewer's Signature) (Date)