

Special 510(k): Device Modification OIVD Review Memorandum

To: The File

Re: k080916

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

1. The name and 510(k) number of the SUBMITTER'S previously cleared device.

SEBIA CAPILLARYS URINE, PN 2012, software release 5.40 (k070486)

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 (labeling changes are permitted as long as they do not affect the intended use).

There are no changes in Intended Use of Indications for Use (Section).

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 modifications were:

- a) Upgrade of software to the 5.50 release to allow for an automated, as opposed to a manual, method for processing urine samples.
 - b) Change from 200µl of samples manually applied to uncolored dilution segments to 100µl of samples automatically applied to green dilution segments for analysis.
 - c) Additional step of normalizing capillaries with the Normal Control Serum, SEBIA, PN 4785, prior to starting a new analysis sequence. The Normal Control Serum is now diluted 80, as opposed to 40 times, in working dialysis buffer.
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and

Similarities:

Feature	Modified Device
Intended Use	No Change
Fundamental Scientific Technology	No Change
Design Assay Detection	No Change
Performance	No Change

Differences:

- a) Upgrade software from 5.40 to 5.50
- b) Automated, as opposed to a manual, method for processing urine samples.
- c) Change from 200 µL of samples manually applied to uncolored dilution segments to 100 µL of samples automatically applied to green dilution segments for analysis.

- d) Additional step of normalizing capillaries with the Normal Control Serum (SEBIA, PN 4785), prior to starting a new analysis sequence.
- e) The Normal Control Serum is diluted 80, as opposed to 40 times, in working dialysis buffer.

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.

Sebia used failure mode and effect analysis (FMEA) (page 6-7).

- 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.

These are listed as part of the failure mode and effect analysis (FMEA) (pages 6-7).

- 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 (Page 220).
 - 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 (Page 221).

6. A **Truthful and Accurate Statement**, a **510(k) Statement** and the **Indications for Use Enclosure**.

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 device.