

SPECIAL 510(k): Device Modification OIR Decision Summary

To: THE FILE

RE: DOCUMENT NUMBER k162395

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): **MP DOA-10 Panel Test Cup and MP DOA-11 Panel Test Cup.**

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

k003809 Rapid Drugs of Abuse Single and Multiple Test Panels
k033566 MICROMEDIC Drugs of Abuse Panel Test
k051958 RapidBUP Test Strip / RapidOXY Test Strip

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 to combine previously cleared, prescription use, drugs of abuse test strips into a new test format that combines either 10 or 11 different tests into a single cup format as well as increase the total time the test strips are in contact with the sample matrix. The predicate devices are labeled for 20 seconds of contact with the sample matrix; the new device is labeled for 5 minutes of contact with the sample matrix.
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and device 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
 - 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 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.