SPECIAL 510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K243498

B Applicant

Microgenics Corporation

C Proprietary and Established Names

Alinity c Benzodiazepines Reagent Kit

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
JXM	Class II	21 CFR 862.3170 - Benzodiazepine Test System	TX - Clinical Toxicology

II Review Summary:

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. DRI Benzodiazepine Assay (K173963)

2. Submitter's statement that the **INDICATIONS FOR USE/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).

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 modification was to extend the validation of the Alinity c Benzodiazepines Reagent Kit from its predicate (named DRI Benzodiazepine Assay) on the Beckman Coulter AU680 Clinical Chemistry Analyzer (K173963) to the Alinity c Analyzer System (K243498). The assay intended for the qualitative and/or semiquantitative determination of the presence of benzodiazepines and their metabolites in human urine at a cutoff concentration of 200 ng/mL (0.700 µmol/L) remains the same.

4. Comparison Information (i.e., similarities and differences) to the submitter's legally marketed predicate device including, labeling, intended use, and physical characteristics.

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.

6. 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 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.