

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE**

A. 510(k) Number:

K041073

B. Purpose for Submission:

New Device

C. Analyte:

Quality control material (assayed and unassayed)

D. Type of Test:

Quantitative

E. Applicant:

Microgenics Corp.

F. Proprietary and Established Names:

DOCUMENT® Salicylate CAL· VER

G. Regulatory Information:

1. Regulation section:
21 CFR 862.1660; Quality control material (assayed and unassayed)
2. Classification:
Class I
3. Product Code:
JJX
4. Panel:
75

H. Intended Use:

1. Intended use(s):
The DOCUMENT® Salicylate CAL· VER® solutions are intended for in vitro diagnostic use in the quantitative determination of linearity, calibration, verification, verification of Analytical Measurement Range (AMR) and verification of the reportable range on immunochemistry and clinical chemistry systems for salicylate. Multiple levels are provided to establish the linear relationship between theoretical operation and actual performance. There exists a linear relationship among each of the solutions.
2. Indication(s) for use:
The DOCUMENT® Salicylate CAL· VER® solutions are intended for in vitro diagnostic use in the quantitative determination of linearity, calibration,

verification, verification of Analytical Measurement Range (AMR) and verification of the reportable range on immunochemistry and clinical chemistry systems for salicylate. Multiple levels are provided to establish the linear relationship between theoretical operation and actual performance. There exists a linear relationship among each of the solutions.

3. Special condition for use statement(s):
Not applicable
4. Special instrument Requirements:
Not applicable

I. Device Description:

The DOCUMENT® Salicylate CAL· VER® set consists of 5 levels with 5 mL per level of solutions containing salicylate- Levels 1 through 5- with concentrations ranging between 0 to approximately 100 mg/dL salicylate. The base matrix for these solutions is human serum with preservatives added for stability.

J. Substantial Equivalence Information:

1. Predicate device name(s):
DOCUMENT® Thyroid CAL· VER®
2. Predicate K number(s):
K992034
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	Assayed or unassayed quality control	Assayed quality control
Matrix	Human Serum	Human Serum
Control Form	Liquid	Liquid
Storage	2°C to 8°	2°C to 8°
Differences		
Item	Device	Predicate
Analytes	Salicylate	Thyroxine (T4) Triiodothyronine (T3) Thyroid Stimulating Hormone (TSH)
Control Levels	Five target levels	Eight target Levels

K. Standard/Guidance Document Referenced (if applicable):

L. Test Principle: NA

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
 - a. *Precision/Reproducibility:*

- Not Applicable
- b. Linearity/assay reportable range:*
Not Applicable
- c. Traceability (controls, calibrators, or method):*
USP standard
- d. Detection limit:*
Not Applicable
- e. Analytical specificity:*
Not Applicable
- f. Assay cut-off:*
Not Applicable

2. Comparison studies:

- a. Method comparison with predicate device:*
The control was compared with the SYNCRON systems Salicylate reagent on a SYNCHRON CX4 analyzer. Twenty-one replicates were analyzed in three runs for each level and resulted in coefficient of variation deviations of less than 10%.
- b. Matrix comparison:*
Not Applicable

3. Clinical studies:

- a. Clinical sensitivity:*
Not Applicable
- b. Clinical specificity:*
Not Applicable
- c. Other clinical supportive data (when a and b are not applicable):*
Not Applicable

4. Clinical cut-off:

Not Applicable

5. Expected values/Reference range:

The concentrations in the DOCUMENT® Salicylate CAL· VER® set has lot specific values that range from 0 to 100 mg/dL.

N. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.