SECTION II

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number:

Submitter:
Microgenics Corporation
46360 Fremont Blvd
Fremont, CA 94538
Telephone: (510)-979-5012
Facsimile: (510) 979-5212

Contact Person:
David Casal, Ph.D.
Vice-President, Clinical, Regulatory and Quality Affairs
Telephone: (510)-979-5012
Facsimile: (510) 979-5212

Preparation Date:
April 21, 2004

Device Information:

Device Classification Name: Single (Specified) Analyte Control (assayed and unassayed)
Device Description: Quality control material (assayed and unassayed)
Proprietary Name: DOCUMENT® Salicylate CAL-VER®
Regulation Number: 21 CFR§862.1660
Product Code: JJX
Regulatory Class: Class I

Predicate Devices:

Evaluation of the data and results enclosed herein demonstrate that the DOCUMENT® Salicylate CAL-VER® set is substantially equivalent in form and function to the DOCUMENT® Thyroid CAL-VER® set (K992034) for its stated intended use.
**Device Description:**

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

**Intended 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.

**Comparison to Predicate Device(s):**

The DOCUMENT® Salicylate CAL-VER® Kit is substantially equivalent to the DOCUMENT® Thyroid CAL-VER® (K992034), also manufactured by Microgenics (CASCO) and previously cleared by FDA, for its stated intended use.

<table>
<thead>
<tr>
<th>Device Characteristics</th>
<th>Subject Device</th>
<th>Predicate Device (K992034)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Intended Use</strong></td>
<td>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.</td>
<td>DOCUMENT® Thyroid CAL-VER® contains assayed solutions for in vitro diagnostic use in the quantitative determination of linearity, calibration verification and verification of reportable range on immunochemistry systems and clinical chemistry systems for the following analytes: Thyroxine (T4), Triiodothyronine (T3) and Thyroid Stimulating Hormone (TSH). This product is not intended for use as a calibration material on instrument systems or as a routine quality control material.</td>
</tr>
<tr>
<td><strong>Analytes (by configuration)</strong></td>
<td>Salicylate</td>
<td>Thyroxine (T4), Triiodothyronine (T3) Thyroid Stimulating Hormone (TSH)</td>
</tr>
<tr>
<td><strong>Matrix</strong></td>
<td>Human Serum</td>
<td>Human Serum</td>
</tr>
<tr>
<td><strong>Control Form</strong></td>
<td>Liquid</td>
<td>Liquid</td>
</tr>
<tr>
<td><strong>Control Levels</strong></td>
<td>Five target levels ranging from 0 to approximately 100 mg/dL</td>
<td>Eight levels across the reportable range</td>
</tr>
<tr>
<td><strong>Storage</strong></td>
<td>2°C to 8°C until expiration date</td>
<td>2°C to 8°C until expiration date</td>
</tr>
<tr>
<td><strong>Stability</strong></td>
<td>Until expiration date noted on vial label.</td>
<td>Until expiration date noted on vial label.</td>
</tr>
</tbody>
</table>

**Summary:**
The information provided in this pre-market notification demonstrates that the DOCUMENT® Salicylate CAL.VER® kit is substantially equivalent in form and function to the DOCUMENT® Thyroid CAL.VER® (K992034) for its stated intended use. Substantial equivalence was demonstrated through comparison of intended use and physical properties of the subject device to the commercially available predicate device. The information supplied in this pre-market notification provides reasonable assurance that DOCUMENT® Salicylate CAL.VER® kit is safe and effective for its stated intended use.
MAY 21 2004

David Casal, Ph.D.
Vice President, Clinical, Regulatory and Quality Affairs
Microgenics Corp.
46360 Fremont Blvd.
Fremont, CA 94538

Re: k041073
Trade/Device Name: DOCUMENT® Salicylate CAL-VER® Kit
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality Control material (assayed and unassayed)
Regulatory Class: Class I
Product Code: JJX
Dated: April 21, 2004
Received: May 10, 2004

Dear Dr. Casal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA’s issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act’s requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure
SECTION III
INDICATIONS FOR USE STATEMENT

510(k) Number (if known): k041073

Device name: DOCUMENT® Salicylate CAL.VER® Kit

Indications 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.

Ruth Chalm for Carol Benson
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) k041073

Prescription Use X AND/OR Over-the Counter Use
(Part 21 CFR §801 Subpart D) (21 CFR §807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)