**Thermo**DMA

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JUL 2 5 2002

## 510 (k) Summary

This Summary of Safety and Effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

**Submitter:** Thermo DMA, Inc.

**Address:** 845 Avenue G East
Arlington, Texas 76011

**Contact Person:** Thomas Dollar, Manager of Regulatory Affairs

**The assigned 510(k) number is** K022108

**Product Code:** JIX, Calibrator, Multi-Analyte Mixture

**Device Name:** Thermo DMA Data-Cal

**Device Class:** II

**Predicate Device:** Data Medical Associates (DMA) Data-Cal

**Description and Intended Use:** Thermo DMA's Data-Cal is intended for use as a reference material in the single point calibration of clinical chemistry procedures.

**Clinical Significance :**
A calibrator is a device intended for medical purposes for use in a test system to establish points of reference that are used in the determination of values in the measurement of substances in serum specimens.

**Methodology:**
Thermo DMA Data-Cal Calibrator is to be used in clinical chemistry assays where it reacts in a manner equivalent to corresponding components present in serum samples.

**Substantial Equivalence - Similarities:**

| **Feature** | New calibrator | Current calibrator (Predicate device) |
|---|---|---|
| **Intended Use** | For the quantitative calibration of clinical chemistry assays. | For the quantitative calibration of clinical chemistry assays. |
| **Format** | Pooled human sera with constituents added as required to obtain levels. | Pooled human sera with constituents added as required to obtain levels. |
| **Stability** | Stable at 2-8 °C until expiration expiration date. | Stable at 2-8 °C until expiration date. |
| | Stable for seven days after reconstitution. | Stable for five days after reconstitution. |

| Feature | New calibrator | Current calibrator (Predicate device) |
|---|---|---|
| **Levels** | single level | single level |
| **Physical State** | lyophilized | lyophilized |

**Differences**

There are no significant differences between the two products.

**Protocol for accelerated stability: [See Table I - Stability Data]**

The product was put at 37° C for 21.5 days. According to the Thermo DMA SOP for Accelerated Stability Testing (SOP #20) this time period is equivalent to 36 months when stored at 2-8° C. After the accelerated storage interval the calibrator was reconstituted and compared to material that had been stored at 2-8° C. Both the stressed and non-stressed materials were then assayed seven days after reconstitution to validate the proposed reconstitution stability claim. In addition to this accelerated evaluation the manufacturer of the calibrator material has documented real time stability data for calibrators of equivalent composition.

Samples of the calibrator material will be held for real time stability testing at Thermo DMA.

**Process for value assignment and validation**

The values were assigned for this calibrator by assaying the calibrator as unknowns in analyte specific reagents. The assays were calibrated against NIST primary standards where available. In order to insure that vial-to-vial variability was properly evaluated, duplicate tests were run on ten vials. Results obtained in this evaluation were consistent with those obtained in testing conducted on equivalent predicate devices.

**Instruments and statistical analysis: [See Table II - Set Points]**

For purposes of obtaining data for this protocol Thermo DMA conducted tests using standard procedures applicable to the Roche Hitachi 717 to generate analyte values. Each unknown was assayed in two separate runs using different lot numbers of reagents. These unknowns were run after they had been stored at 2-8° C and at 37° C. The analyte set points for the calibrator were determined by calculating the mean value of twenty replicates.

When subsequent calibrator lots are produced for market distribution, testing will be conducted utilizing multiple analyzers.

**Traceability**

The analyte values obtained are traceable to NIST material where available. Primary standards were incorporated into testing protocols in order to support accuracy and traceability. These Primary Standards were produced in house utilizing NIST Standard Reference Materials (SRM) in accordance with procedures provided by NIST.

**Traceability - (continued)**

Where NIST SRM's were not available for use in testing, standards were prepared using high purity materials in accordance with established clinical chemistry analytical procedures. These secondary methods have an established history of providing standards with known performance characteristics.

The following SRM materials were utilized in the production of Primary Standards employed;

| | Analyte | SRM # |
|---|---|---|
| a. | $CO_2$ | SRM 192b |
| b. | Bilirubin | SRM 916a |
| c. | BUN | SRM 912a |
| d. | Calcium | SRM 915a |
| e. | Chloride | SRM 919a |
| f. | Cholesterol | SRM 911b |
| g. | Creatinine | SRM 914a |
| h. | Glucose | SRM 917a |
| i. | Iron | SRM 937 |
| j. | Magnesium | SRM 929 |
| k. | Phosphorus | SRM 186-I-f |
| l. | Uric Acid | SRM 913 |

**Performance transfer: [See Table III - Verification]**

In the case of each analyte the value of the secondary calibrator was determined by assaying it as an unknown sample while calibrating with a primary calibrator. After target values were established, the secondary calibrator was then used to calibrate an assay, which included a primary calibrator when possible.

If no primary standard was available a calibrator from a vendor (Verichem, Inc.) that currently manufacturers and distributes similar products was incorporated into the assay protocol. All verification runs included a serum-based standard from Verichem to confirm that an accurate set point had been determined.

Thermo DMA also included NIST SRM #909b into the testing protocols where appropriate. Our criteria when calibrating against the secondary calibrator was to obtain the set point for the SRM or Verichem within +/- 10%. This criterion was met in all cases except for instances in which the value established fell below one, and in the case of Triglyceride SRM #909b, Level 1 which recovered 14%. Thermo DMA feels that the triglyceride set point is valid due to the facts that the Verichem material recovers within 6% and the previous lot of calibrator recovers its established set point. Samples of the predicate calibrator were also included in test protocols, the results of which were consistent with historic performance data.

**Conclusion:** Analysis of the comparative measurements and stability data presented in the 510(k) submission for this calibrator, demonstrates the Thermo DMA Data-Cal Calibrator is safe and effective. No significant differences exist between the results obtained on tests conducted utilizing the Thermo DMA Data-Cal when compared to those obtained when utilizing the predicate device in these studies.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 2 5 2002

Mr. Thomas Dollar
Manager of Regulatory Affairs
Thermo DMA
845 Avenue G East
Arlington, TX 76011-7709

Re: k022108
Trade/Device Name: Thermo DMA Data-Cal Calibrator
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIX
Dated: June 27, 2002
Received: June 28, 2002

Dear Mr. Dollar:

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 the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 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 advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## INDICATIONS FOR USE STATEMENT

**510(K) Number** K022108

**Device Name: Thermo DMA Data-Cal Calibrator**

**Indications for Use: The Thermo DMA Data-Cal Calibrator is intended for use in the calibration of clinical chemistry assays.**

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K022108

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

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**concurrence of CDRH, Office of Device Evaluation (ODE)**

**Prescription Use** X **OR** **Over-the Counter-Use** _____
**(Per 21 CFR 801.109)**