

K982217

July 2, 1998

510(k) SUMMARY

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

The assigned 510(k) number is: _____.

Contact Name: Roy F. Schall, Jr., Ph.D.

Date: June 11, 1998

Product Name: AC/ADtm Linearity Verifiers

Common Names: Calibration Verifiers, Linearity Verifiers

Predicate Devices: ABCtm Linearity Verifiers by SC Calibrators & Controls LLC

Description of the Device: AC/AD Linearity Verifiers is a in vitro diagnostic medical device intended for use with automated and manual methods monitoring selected therapeutic drugs (TDM). AC/AD Linearity Verifiers is a five level, multiconstituent set of calibrators made in human serum and used to confirm the proper calibration, linear operating range and reportable range (linearity) of TDM methods. The "AC/AD" designation derives from AntiConvulsant, antiAnxiety and other Drugs. AC/AD Linearity Verifiers contains concentrations of analytes extending over a wide analytical range. Level 1 is a zero level, and level 5 has a concentration near the upper limit of instruments. Levels 1, 2, 3, and 4 are related by linear dilution. When assayed like patient samples, the verifiers assist in determination of calibration and linear operating range (linearity) of methods for the analytes included.

Intended Use: AC/AD Linearity Verifiers are intended to be used to verify the calibration, linear operating range and reportable range (linearity) of methods used to determine the concentration of therapeutic drugs.

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Technical Characteristics Compared to Predicate Device:

Comparison of Features of AC/AD Linearity Verifiers and the predicate device: ABC Linearity Verifiers.

<u>Attribute</u>	<u>AC/AD Linearity Verifiers</u>	<u>ABC Linearity Verifiers</u>
No of Analytes	11	12
No of Levels	5	5
Vol per level (mL)	5	5
Type of Analytes	Therapeutic Drugs	Therapeutic Drugs
Method(s)	Automated, Manual Immunoassay, other (except EMIT ethosuximide)	Automated, Manual Immunoassay, other
Base Matrix	Human Serum	Human Serum
Preservative	Non-Azide (proprietary)	Non-Azide (proprietary)
Calibration	Gravimetric & Traceable	Gravimetric + Some Traceable
Use	Verification of Calibration, Linear Operating Range (OR), Reportable Range All Methods (except EMIT ethosuximide)	Verification of Calibration, Linear Operating Range (OR), Reportable Range All Methods

Technical Characteristics by Assessment of Performance: The performance of AC/AD Verifiers has been tested on three commonly used automated therapeutic drug monitoring systems (Abbott TDx Assay System, Dade-Behring (formerly Syva) EMIT system, and Roche-Boehringer CEDIA reagents), by two colorimetric methods (GED reagents for acetaminophen and Sigma Diagnostic reagents for salicylate) and by HPLC (for nordiazepam) to validate their use. Most methods tested demonstrated the desired functionality of the product. Carbamazepine by fluorescence polarization immunoassay demonstrated a significant miscalibration believed to be real. GED reagents for acetaminophen gave results which might indicate incompatibility with AC/AD verifiers. However, the GED reagents gave a level-correlated, proportional colorimetric response with the verifiers, and it was not possible to rule out a miscalibration. EMIT reagents for ethosuximide reacted with an interferent in the AC/AD base matrix, and this product is not useful with the EMIT ethosuximide reagents.

Conclusions: Based upon the purpose of the device, the descriptions and labeling of the predicate device, and upon the safety and efficacy using multiple instruments and methods, and stability data generated for the AC/AD Linearity Verifiers, the product is substantially equivalent to the predicate device.





JUL 2 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SC Calibrators & Controls LLC
C/O Ms. Carole Stamp
TUV Product Service
1775 Old Highway 8 NW, Suite 104
New Brighton, Minnesota 55112-1891

Re: K982217
Trade Name: AC/AD™ Linearity Verifiers
Regulatory Class: I
Product Code: DIF
Dated: June 23, 1998
Received: June 24, 1998

Dear Ms. Stamp:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Pre-market Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2

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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "dsmo@fdadr.cdrh.fda.gov".

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

2

510 (k) NUMBER (IF KNOWN) : _____

DEVICE NAME: **AC/AD Linearity Verifiers**

Indications for Use of the Subject Device: AC/AD Linearity Verifiers should be used any time it is necessary to confirm the proper calibration and linear operating range of TDM methods and instruments. Quality control/verification requirements should be determined in conformance with local, state and/or Federal regulations or accreditation requirements

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use _____
(Optional Format 1-2-96)

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