

OCT 14 1997

K973791

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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: August 31, 1997

Product Name: ABCtm Calibration Verifiers

Common Names: Calibration Verifiers, Linearity Verifiers

Predicate Devices: Document TDM I Linearity Set, Casco Standards, Inc.
LiniCAL Protein I Calibration Verifiers, International Enzymes, Inc.

Description of the Device: ABC Calibration Verifiers is an in vitro diagnostic medical device intended for use with automated and manual methods monitoring selected therapeutic drugs (TDM). ABC Calibration Verifiers is a five level set of verifiers, with each level containing 12 analytes, is made with human serum and is used to confirm the proper calibration, linear operating range and reportable range (linearity) of TDM methods. The "ABC" designation derives from Antibiotic and Cardiac drugs. ABC Calibration Verifiers contains concentrations of analytes extending over a wide analytical range. Level 1 is a zero level, and level 5 has concentrations near the upper limit of instruments. Levels 2, 3, and 4 are targeted to be near analyte concentrations of clinical interest. When assayed like patient samples, the verifiers assist in determination of calibration and linear operating range (linearity) of methods for the analytes included. (A second product, ABC Linearity Verifiers, is identical in every respect to this product except that the concentrations of levels 1,2,3, and 4 are related by linear dilution. Both products will perform linear range and calibration verification, and their composition, stabilities and performance are identical except for concentration of middle levels.)

Intended Use: ABC Calibration Verifiers is 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.

Technical Characteristics Compared to Predicate Devices:

Comparison of Features of ABC Calibration Verifiers and the two predicate devices: DOCUMENT TDM I Linearity Test Set and LiniCAL Protein I Calibration Verifiers.

<u>Attribute</u>	<u>ABC Calibration Verifiers</u>	<u>DOCUMENT TDM I</u>	<u>LiniCAL Protein I</u>
No Analytes/bottle	12	19	6
No of Levels/set	5	8	5
Vol per level (mL)	5	5	1
Type of Analytes	Therapeutic Drugs	Therapeutic Drugs	Serum Proteins
Method(s)	Automated, Manual Immunoassay, other	Automated Immunoassay	Beckman Array Nephelometer
Base Matrix	Human Serum	Human Serum	Human Serum
Preservative	Non-Azide	Azide	Azide
Calibration	Gravimetric + Some Traceable	Assayed (Two Methods)	Assayed + Traceable
Use	Verification of Calibration, Linear Operating Range (OR), Reportable Range All Methods	Verif. of Calib, Linear OR, Reportable Range for Two Methods	Verif. of Calib, Linear OR Beckman Array
Stability	60 days at 2-8 ^o C; To Expir. Date if frozen (Vancomycin 30 days 2-8 ^o C)	To Expiration at 2-8 ^o C	To Expiration Date unopened at 2-8 ^o C; 14 days opened

Technical Characteristics by Assessment of Performance: The performance of ABC Verifiers has been tested on two commonly used automated therapeutic drug monitoring systems (Abbott TDx Assay System and Behring (formerly Syva) EMIT system reagents) and by HPLC methods for selected analytes to validate their use. All methods tested demonstrated the desired functionality of the product.

Conclusions: Based upon the purpose of the device, the descriptions and labeling of the predicate devices, and upon the safety and efficacy using multiple instruments and methods, and stability data generated for the ABC Calibration Verifiers, the

product is substantially equivalent to the predicate devices.



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Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SC Calibrators & Controls LLC
Ms. Carole Stamp
c/o TUV Product Service
1775 Old Highway 8
New Brighton, MN 55112-1891

Re: K973791
Trade Name: ABC™ Calibration Verifiers™
Regulatory Class: I
Product Code: JJY
Dated: September 19, 1997
Received: October 6, 1997

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 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 (Premarket 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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 - Ms. Stamp

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

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 at (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



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

12.0 INDICATIONS FOR USE STATEMENT

The Office of Device Evaluation (ODE) has developed the attached optional form to assist them with instituting the requirement for all original 510(k)s received by ODE on or after 1/2/96.

The requirement is for all 510(k) submissions to have clearly defined "Indications for Use". These indications will be attached by ODE to any substantial equivalence (SE) letter to define what the device is cleared for.

No 510(k) submitted on or after 1/2/96 will be cleared for marketing by ODE without the inclusion of the indications for use information, which will be attached to an SE letter.

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): _____

Device Name: ABCTM Calibration Verifiers

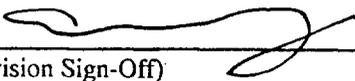
Indications For Use:

Indications For Use

ABC Calibration Verifiers should be used any time it is necessary to confirm the proper calibration and linear operating range of TDM methods and instruments. The Clinical Laboratory Improvement Act and its regulations (CLIA) require verification of linearity and calibration twice a year for modified moderately complex methods, highly complex methods and in-house methods. Verification should be performed more often if any of the following occurs: introduction of procedures for which control values change with a new reagent lot, major preventative maintenance or replacement of critical parts on the instrument, control values exhibit an unusual trend or shift or are outside the acceptable limits of the laboratory, and if the laboratory's schedule of verification is more frequent.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number K 973791

Description Use ✓

OR

Over-The-Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)