



K961659

Diagnostics

510(k) Summary

Introduction According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

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2. Device name Proprietary name: CEDIA Core TDM Multi-Cals

Common name: Therapeutic drug monitoring calibrators for use in the calibration of the CEDIA assays for carbamazepine, phenobarbital, phenytoin, theophylline, and valproic acid.

Classification name: Calibrators, drug mixture

3. Predicate device The Boehringer Mannheim CEDIA Core TDM Multi-Cals are substantially equivalent to the kit calibrators included in CEDIA Carbamazepine (K914857), Phenobarbital (K904413), Phenytoin (K905689), Theophylline (K961462), and Valproic Acid (930734/2) Assays..

4. Device Description The CEDIA Core TDM Calibrators are manufactured using bovine serum albumin, carbamazepine, phenobarbital, phenytoin, theophylline, valproic acid, stabilizers, and preservatives. The drugs are appropriately spiked into the calibrator matrix to the correct calibrator concentration levels. The calibrators are in process checked and quality controlled against in-house reference calibrators (prepared using a similar procedure) which have been value assigned by comparison to the predicate device to ensure correct assay calibration.

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5. Intended use

The CEDIA Core TDM Multi-Cals are used to calibrate the CEDIA assays for carbamazepine, phenobarbital, phenytoin, theophylline, and valproic acid in human serum and plasma.

6. Comparison to predicate device

The Boehringer Mannheim CEDIA Core TDM Multi-Cals are substantially equivalent to the CEDIA Carbamazepine (K914857), Phenobarbital (K904413), Phenytoin (K905689), Theophylline (K961462), Valproic Acid (930734/2) Assays.

The following table compares the CEDIA Core TDM Multi-Cals with the predicate devices, CEDIA Carbamazepine, Phenobarbital, Phenytoin, Theophylline, and Valproic Acid assay's kit calibrators. Specific data on the performance of the test have been incorporated into the draft labeling in attachment 5. Labeling for the predicate device is provided in attachment 6.

Similarities:

- Similar formulation.
- Similar concentrations of carbamazepine, phenobarbital, phenytoin, theophylline, and valproic acid.
- For the calibration of the CEDIA Carbamazepine, Phenobarbital, Phenytoin, Theophylline, and Valproic Acid assays.

Differences:

Feature	Core TDM Multi-Cals	Kit Calibrators
Configuration	sold separately from reagents	sold with reagents in kit

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6. Comparison to predicate device, (cont.)

Performance Characteristics:

Feature	Core TDM Multi-Cals	Kit Calibrators
Open Vial Stability	Stable for 30 days	Stable for 30 days

- Method Comparison: equivalent correlation between kit calibrators and CEDIA Core TDM Multi-Cals.
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