

K962269

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**510(k) Summary**

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**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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**1. Submitter name, address, contact** Boehringer Mannheim Corporation  
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Date Prepared: October 25, 1996

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**2. Device name** Proprietary name: CEDIA Cardiac TDM Multi-Cals

Common name: Therapeutic drug monitoring calibrators for use in the calibration of the CEDIA assays for digoxin, N-acetylprocainamide, and procainamide.

Classification name: Calibrators, drug mixture

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**3. Predicate device** The Boehringer Mannheim CEDIA Cardiac TDM Multi-Cals are substantially equivalent to the kit calibrators included in CEDIA Digoxin (K910642), TDx Procainamide (K834464), and TDx N-acetylprocainamide (K830206) Assays.

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**4. Device Description** The CEDIA Cardiac TDM Calibrators are manufactured using bovine serum albumin, digoxin, N-acetylprocainamide, procainamide, 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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## 510(k) Summary, Continued

### 5. Intended use

The CEDIA Cardiac TDM Multi-Cals are used to calibrate the CEDIA assays for digoxin, N-acetylprocainamide, and procainamide, in human serum and plasma.

### 6. Comparison to predicate device

The Boehringer Mannheim CEDIA Cardiac TDM Multi-Cals are substantially equivalent to the kit calibrators included in CEDIA Digoxin (K910642), TDx Procainamide (K834464), and TDx N-acetylprocainamide (K830206) Assays.

The following table compares the CEDIA Cardiac TDM Multi-Cals with the predicate devices, CEDIA Digoxin, TDx Procainamide, and TDx N-acetylprocainamide 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 concentrations of digoxin, N-acetylprocainamide, and procainamide.

#### Differences:

Feature	Cardiac TDM Multi-Cals	Kit Calibrators
Configuration	sold separately from reagents	sold with reagents in kit
Number of calibrators in set (N-acetylprocainamide, Procainamide)	2	6
Matrix	Bovine Serum Albumin	Human Serum

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## 510(k) Summary, Continued

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**6.  
Comparison  
to predicate  
device, (cont.)**

**Performance Characteristics:**

- **Method Comparison:** equivalent correlation between predicate device kit calibrators and CEDIA Cardiac TDM Multi-Cals.
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