

SEP 10 1996



K 963191  
Diagnostics

## 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  
2400 Bisso Lane  
Concord, CA 94524-4117  
(510) 674-0690 extension 8240

Contact Person: Betsy Soares-Maddox

Date Prepared: August 14, 1996

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**2. Device name** Proprietary name: CEDIA Antibiotic TDM Multi-Cals  
Common name: Therapeutic drug monitoring calibrators for use in the calibration of the CEDIA assays for tobramycin and gentamicin.

Classification name: Calibrators, drug mixture

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**3. Predicate device** The Boehringer Mannheim CEDIA Antibiotic TDM Multi-Cals are substantially equivalent to the kit calibrators included in CEDIA tobramycin (K912143) and gentamicin (K913470) assays.

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**4. Device Description** The CEDIA Antibiotic TDM Calibrators are manufactured using bovine serum albumin, tobramycin, gentamicin, 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 Antibiotic TDM Multi-Cals are used to calibrate the CEDIA assays for tobramycin and gentamicin in human serum and plasma.

**6. Comparison to predicate device**

The Boehringer Mannheim CEDIA Antibiotic TDM Multi-Cals are substantially equivalent to the kit calibrators included in CEDIA tobramycin (K912143) and gentamicin (K913470) assays.

The following table compares the CEDIA Antibiotic TDM Multi-Cals with the predicate devices, CEDIA Tobramycin and Gentamicin 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 tobramycin and gentamicin.

**Differences:**

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

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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 Antibiotic TDM Multi-Cals.
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