K971287

MAY - 8 1997

Summary of Safety & Effectiveness
SYNCHRON ® Systems DRUG CALIBRATOR 3 PLUS

1.0 **Submitted By:**

Sheri Hall
Product Submissions Manager
Beckman Instruments, Inc.
200 S. Kraemer Blvd., W-337
Brea, California 92822-8000
Telephone: (714) 993-8961
FAX: (714) 961-4457

2.0 **Date Submitted:**

1 April 1997

3.0 **Device Name(s):**

3.1 **Proprietary Names**

SYNCHRON® Systems DRUG CALIBRATOR 3 PLUS

3.2 **Classification Name**

(21 CFR § 862.1150) Calibrator

4.0 **Predicate Device(s):**

SYNCHRON Systems CAL 3 Plus	Predicate	Predicate Company	Docket Number
SYNCHRON Systems DRUG CALIBRATOR 3 PLUS	SYNCHRON Systems DRUG CALIBRATOR 3	Beckman Instruments, Inc.	K955644

5.0 Description:

The SYNCHRON Systems DRUG CALIBRATOR 3 PLUS is designed for use with clinical chemistry analyzers from Beckman Instruments, such as the SYNCHRON CX® and LX™ Clinical Systems. The SYNCHRON Systems DRUG CALIBRATOR 3 PLUS is for use in the calibration of SYNCHRON Systems Gentamicin and Tobramycin chemistries.

6.0 Intended Use:

The SYNCHRON® Systems DRUG CALIBRATOR 3 PLUS, when used in conjunction with SYNCHRON Gentamicin Reagent and Tobramycin Reagent, is intended for use on the SYNCHRON Systems and for the calibration of gentamicin and tobramycin.

7.0 Comparison to Predicate(s):

The SYNCHRON Systems DRUG CALIBRATOR 3 PLUS is a liquid human serum matrix to which gentamicin and tobramycin are added. The SYNCHRON Systems DRUG CALIBRATOR 3 (six level set) contained only gentamicin. The SYNCHRON Systems DRUG CALIBRATOR 3 PLUS will contain both gentamicin and tobramycin into a single, six level, calibrator set. The SYNCHRON Systems DRUG CALIBRATOR 3 PLUS is intended to be used on Beckman's SYNCHRON Systems.

8.0 Summary of Performance Data:

The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence of the SYNCHRON Systems DRUG CALIBRATOR 3 PLUS to the SYNCHRON Systems DRUG CALIBRATOR 3 and is stable for gentamicin and tobramycin. The value assignment process for each analyte demonstrates the ability to recover weighed in analyte levels which can be correlated to a known standard via the anchor method.

SYNCHRON Systems DRUG CALIBRATOR 3 PLUS

Stability Testing Summary

Stress Temperature	Duration of Incubation	Predicted Stability	Beckman Stability Claim*
25°C	60 Days	30 Months	24 Months
37°C	21 Days	30 Months	24 Months
45°C	10 Days	30 Months	24 Months

*** Expiration dating placed on the package based on date of manufacture**

This summary of safety and effectiveness is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and the implementing regulation 21 CFR 807.92.