

BECKMAN

Appendix C
Summary of Safety & Effectiveness
SYNCHRON® Systems Cannabinoid 20 ng Reagent

APR - 3 1995

K955677

1.0 **Submitted By**

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2.0 **Date Submitted**

15 December 1995

3.0 **Device Name(s)**

3.1 **Proprietary Names**

SYNCHRON Systems Cannabinoids 20 ng (THC2) Reagent
SYNCHRON Systems DAT Negative Urine Calibrator
SYNCHRON Systems 20 ng/mL THC Urine Calibrator
SYNCHRON Systems 50 ng/mL THC Urine Calibrator
SYNCHRON Systems 0 ng/mL THC Urine Control
SYNCHRON Systems 50 ng/mL THC Urine Control

3.2 **Classification Names**

Cannabinoid test system (21 CFR 862.3870)

4.0 **Predicate Device(s)**

Emit II Cannabinoid 20 ng Assay, Syva Company, K940158
Cannabinoid Reagent, Diagnostic Reagents, Inc, K943998
THC Urine Calibrators and Controls, Diagnostic Reagents, Inc., K944701

5.0 **Description**

The SYNCHRON Cannabinoid 20 ng Reagent is an enzyme immunoassay reagent test kit for the SYNCHRON Systems and provides a rapid screening procedure for determining the presence of cannabinoids and its metabolites in urine. It is designed to complement the current panel of CX Drugs of Abuse Assays, previously cleared by FDA. The kit consists of reagent and calibrators.

6.0 **Intended Use**

The SYNCHRON Systems Cannabinoid 20 ng Reagent, in conjunction with the SYNCHRON Systems THC Urine Calibrators, is intended for use in the qualitative determination of cannabinoids in human urine samples. This assay is designed for use with the family of SYNCHRON Systems, which include analyzers such as the SYNCHRON® CX4, CX®4CE, CX4 DELTA, CX5, CX5CE, CX5 DELTA, CX7, and CX7 DELTA Systems.

7.0 Comparison to Predicate(s)

The following table shows similarities and differences between the predicates identified in Section 4.0 of this summary.

SYNCHRON Cannabinoid Reagent	Emit II Cannabinoid Reagent
Similarities	
Homogeneous enzyme immunoassay intended for the qualitative analysis of cannabinoids in human urine	Same
Method based on competition between drug in the sample and drug labeled with the enzyme G6PDH; enzyme activity measured as NAD is converted to NADH	Same
Reagent designed for chemistry analyzers which maintain constant reaction temperature, use automated pipetting, measure enzyme rates, mix, and accurately time reactions	Same
Reagent provides preliminary analytical test for screening purposes	Same
Differences	
SYNCHRON reagent is liquid stabilized and requires no preparation	Emit II reagent is lyophilized and requires reconstitution
SYNCHRON reagent is intended for qualitative determinations only	Emit II reagent has a specialized application for semi-quantitative determination of drug concentration
SYNCHRON reagent is stable for 60 days once opened, when stored properly	Emit II reagent is stable for 12 weeks once opened, if handled as directed

8.0 Summary of Performance Data

The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to chemistry test systems already in commercial distribution. Equivalence is demonstrated through method comparison, stability, and imprecision experiments that relate results obtained from the SYNCHRON Systems Cannabinoid 20 ng Reagent to the Emit II Reagent.

Relative Sensitivity and Specificity Study Results
 SYNCHRON Cannabinoid 20 ng Reagent vs Emit II

Overall Agreement	99%
Relative Sensitivity	99%
Relative Specificity	100%
Number of Disconcordant w/ Emit II	1
Total Number of Samples	136

SYNCHRON Cannabinoid 20 ng Reagent Stability Study Results

Product Claim	510(k) Summary
Shelf-life	12 months unopened
On-Instrument Stability	60 days
Calibration Frequency	7 days

Estimated Within-Run Imprecision
SYNCHRON Cannabinoid 20 ng Reagent

Material	Mean (mA/min)	SD (mA/min)	%CV	Number of Results
Negative Calibrator	245	0.8	0.3	20
Control 1 (0 ng/mL)	245	0.8	0.3	20
Low Calibrator (20 ng/mL)	274	0.9	0.3	20
Control 2 (50 ng/mL)	318	1.0	0.3	20
High Calibrator (50 ng/mL)	318	1.1	0.3	20

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.