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Appendix C
Summary of Safety & Effectiveness
SYNCHRON® Systems Methaqualone Reagent

K955676

1.0 Submitted By

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2.0 Date Submitted

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3.0 Device Name(s)

3.1 Proprietary Names

SYNCHRON Systems Methaqualone (METQ) Reagent
SYNCHRON Systems DAT Negative Urine Calibrator
SYNCHRON Systems DAT Low Urine Calibrator II
SYNCHRON Systems DAT High Urine Calibrator II
SYNCHRON Systems DAT Low Urine Control II
SYNCHRON Systems DAT High Urine Control II

3.2 Classification Names

Methaqualone test system (21 CFR 862.3630)
Toxicology calibrator (21 CFR 862.3200)
Toxicology control (21 CFR 862.3280)

4.0 Predicate Device(s)

Emit II Methaqualone Assay, Syva Company, K921013
Methaqualone Reagent, Diagnostic Reagents, Inc, K940123
Urine Calibrator and Controls, Diagnostic Reagents, Inc., K935101

5.0 Description

The SYNCHRON Methaqualone Reagent is an enzyme immunoassay reagent test kit for the SYNCHRON Systems and provides a rapid screening procedure for determining the presence of Methaqualone and it's 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 Methaqualone Reagent, in conjunction with the SYNCHRON System DAT Urine Calibrators, is intended for use in the qualitative determination of

Methaqualone in human urine samples. This assay is designed for use with the family of SYNCHRON Systems, which include analyzers such as the SYNCHRON CX®4, 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 Methaqualone Reagent	Emit II Methaqualone Reagent
Similarities	
Homogeneous enzyme immunoassay intended for the qualitative analysis of Methaqualone 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 Methaqualone Reagent to the Emit II Reagent.

Relative Sensitivity and Specificity Study Results
CX Methaqualone Reagent vs Emit II

Overall Agreement	94%
Relative Sensitivity	88%
Relative Specificity	100%
Number of Disconcordant w/ Emit II	6
Number of Disconcordant w/ GCMS	0
Total Number of Samples	103

SYNCHRON Methaqualone 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 Methaqualone Reagent

Material	Mean (mA/min)	SD (mA/min)	%CV	Number of Results
Negative Calibrator	117	0.8	0.6	20
Control 1 (200 ng/mL)	216	1.1	0.5	20
Low Calibrator (300 ng/mL)	243	0.9	0.4	20
Control 2 (375 ng/mL)	265	1.0	0.4	20
High Calibrator (1000 ng/mL)	290	0.9	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.