

K971203

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Summary of Safety & Effectiveness
SYNCHRON Systems Thyroxine (T4) Reagent

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 Thyroxine (T4) Reagent

3.2 **Classification Name**

Total thyroxine test system (21 CFR § 862.1700)

4.0 **Predicate Device(s):**

SYNCHRON Reagent	Predicate	Predicate Company	Docket Number
SYNCHRON Systems Thyroxine (T4) Reagent	CEDIA T4 MAb Reagent	Boehringer Mannheim Corp.,	K935880
SYNCHRON Systems Thyroxine (T4) Reagent	CEDIA T4 MAb Reagent- SYNCHRON Application	Boehringer Mannheim Corp.,	K942575

5.0 **Description:**

The SYNCHRON Systems Thyroxine (T4) Reagent kit, which includes the T4 Reagent and the T4 Calibrators, is intended for use on Beckman's SYNCHRON Clinical Systems.

6.0 **Intended Use:**

The SYNCHRON Systems Thyroxine (T4) Reagent is intended for the quantitative determination of total thyroxine concentrations in serum on SYNCHRON Clinical Systems.

7.0 **Comparison to Predicate(s):**

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

SIMILARITIES to the PREDICATE

Reagent	Aspect/Characteristic	Comments
SYNCHRON Systems Thyroxine (T4) Reagent	Intended use	Same as the predicate
	Chemical Reaction	Same principle as the predicate
	Formulation	Same source, processing as predicate
	Calibration	Same as the predicate
	Reagent Kit Configuration	Same as the predicate

DIFFERENCES from the PREDICATE

Reagent	Aspect/Characteristic	Comments
SYNCHRON Systems Thyroxine (T4) Reagent	Specimen Type	SYNCHRON T4 Reagent claims Sodium Heparin and Lithium Heparin as acceptable anticoagulants while the Boehringer Mannheim CEDIA T4 MAb Reagent claims Sodium Heparin, Lithium Heparin, and Sodium EDTA as acceptable anticoagulants.

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, imprecision studies, and stability studies that relate results obtained from the SYNCHRON Systems Thyroxine (T4) Reagent and the Boehringer Mannheim CEDIA MAb Thyroxine Reagent with a SYNCHRON Application.

**Method Comparison Study Results
 SYNCHRON Systems T4 Reagent**

Analyte (Reagent)	Slope	Intercept (µg/dL)	r	n	Predicate Method
Thyroxine (T4)	1.018	0.12	0.992	97	Boehringer Mannheim CEDIA MAb Thyroxine Reagent

**Estimated Imprecision
 SYNCHRON Systems T4 Reagent**

Sample	Mean (µg/dL)	S.D. (µg/dL)	%C.V.	N
Within-Run Imprecision				
Level 1	4.2	0.2	4.3	80
Level 2	8.6	0.2	2.4	80
Level 3	17.1	0.3	1.7	80
Total Imprecision				
Level 1	4.2	0.4	8.8	80
Level 2	8.6	0.4	4.3	80
Level 3	17.1	0.4	2.4	80

On-Board Stability Study Results

Reagent	Product Claim
SYNCHRON Thyroxine (T4)	30 days

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.