

BECKMAN

Summary of Safety & Effectiveness SYNCHRON Systems Iron (FE) & Total Iron Binding Capacity (IBCT) Reagents

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 Iron (FE) Reagent
SYNCHRON Systems Total Iron Binding Capacity (IBCT) Reagent

3.2 **Classification Names**

Iron (non-heme) test system (21 CFR 862.1410)
Iron-binding capacity test system (21 CFR 862.1415)

4.0 **Predicate Device(s):**

SYNCHRON CX System Iron (IRON) Reagent, K870986
SYNCHRON CX Systems Total Iron Binding Capacity (TIBC) Reagent, K870986
J&S Medical Associates Micro Column, K893662

5.0 **Description:**

The SYNCHRON Systems Iron (FE) and Total Iron Binding Capacity (IBCT) Reagents are modifications of the current SYNCHRON CX Systems Iron (IRON) and Total Iron Binding Capacity (TIBC) Reagents, and are designed for optimal performance on the SYNCHRON Systems. The modifications include formulation changes which allow for the assay of both serum and plasma samples. Additionally, the IBCT assay utilizes an alumina column for the removal of unbound ferric ions as opposed to magnesium carbonate.

6.0 **Intended Use:**

The SYNCHRON Systems Iron (FE) and Iron Binding Capacity (IBCT) Reagents, in conjunction with SYNCHRON Systems Iron/TIBC Calibrator, are intended for use in the quantitative determination of iron and total iron binding capacity in human serum and plasma samples. These assays are designed for use with the family of SYNCHRON Systems such as the SYNCHRON CX®4, CX®4CE, CX4 DELTA, CX5, CX5CE, CX5 DELTA, CX7, and CX7 DELTA Systems.

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

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

Reagent	Aspect/Characteristic	Comments
SIMILARITIES		
FE Reagent	Timed endpoint reaction using FerroZine Iron Reagent*	Same as SYNCHRON IRON Reagent
	2-year shelf-life, 30-day open bottle, 14-day calibration stability	Same as SYNCHRON IRON Reagent
	Analytic range 5-500 and within-run imprecision claim of 2.5% CV	Same as SYNCHRON IRON Reagent
IBCT Reagent	Supernatant from transferrin saturation is measured by FerroZine Iron Reagent reaction	Same as SYNCHRON TIBC Reagent
	2-year shelf-life, 30-day open bottle, 14-day calibration stability	Same as SYNCHRON TIBC Reagent
	Analytic range 10-1000 and within-run imprecision claim of 4% CV	Same as SYNCHRON TIBC Reagent
DIFFERENCES		
FE Reagent	Sample type for assay	FE reagent modified to utilize <u>serum and plasma samples</u>
IBCT Reagent	Sample type for assay	IBCT reagent modified to utilize <u>serum and plasma samples</u>
	Sample preparation	IBCT reagent utilizes <u>alumina columns for removal of unbound ferric ion</u>

* FerroZine Reagent is a trademark of Hach Chemical Co.

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 FE and IBCT Reagents to the SYNCHRON CX IRON and TIBC Reagents.

Method Comparison Study Results
 SYNCHRON FE & IBCT Reagents vs. SYNCHRON IRON & TIBC Reagents

Analyte	Slope	Intercept	r	Predicate
FE Reagent	1.0158	-0.92	0.9998	CX IRON Reagent
IBCT Reagent	1.0736	-11.95	0.9979	CX TIBC Reagent

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Stability Study Results

Reagent	Product Claim
FE Reagent	24 months shelf-life 30 days on-instrument 14 day calibration
IBCT Reagent	24 months shelf-life 30 days on-instrument 14 day calibration

Estimated Within-Run Imprecision

MATERIAL	MEAN (ug/mL)	SD (ug/mL)	%CV	Number of Results
FE Reagent				
Level 1	53.5	1.41	2.6	80
Level 2	166.5	2.61	1.6	80
Level 3	270.5	2.24	0.8	80
IBCT Reagent				
Level 1	148.2	7.8	5.2	80
Level 2	370.5	4.3	1.2	80
Level 3	448.2	8.7	1.9	80

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.