

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

### Dade Indirect IMT System with TCO<sub>2</sub> Electrode

#### Summary of Safety and Effectiveness

K970330

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The Dade Indirect IMT system with TCO<sub>2</sub> electrode performs four *in vitro* diagnostic tests: sodium (Na), potassium (K), chloride (Cl) and total carbon dioxide (TCO<sub>2</sub>).

The sodium, potassium and chloride (Na/K/Cl) methods use a sample which is diluted automatically on-board the Dimension® XL or RxL clinical chemistry system. The diluted sample is then processed in a multisensor cartridge which uses Integrated Multisensor Technology (IMT) to develop an electrical potential proportional to the activity of each specific ion in the sample. The total carbon dioxide (TCO<sub>2</sub>) method uses a Severinghaus electrode designed to measure the liberated CO<sub>2</sub> from a diluted, acidified sample.

The Dade Indirect IMT system with TCO<sub>2</sub> electrode is substantially equivalent to the Dade direct IMT system (ISE sensor cartridge with revised TCO<sub>2</sub> electrode), which was cleared by the FDA through the 510(k) process. Both systems use integrated multisensor technology on an automated system for the determination of sodium, potassium, chloride and TCO<sub>2</sub> in human serum or plasma, and for determination of sodium, potassium and chloride in urine.

A split sample comparison study was conducted versus another indirect electrolyte system, the Beckman SYNCHRON CX®3 clinical system, with the following results:

	<u>Slope</u>	<u>Intercept</u>	<u>Correlation Coefficient</u>	<u>Range of Samples</u>
<b>Serum/Plasma*</b>				
Na	1.03	-4.8	0.983	98-160
K	1.00	0.06	0.996	2.3-9.5
Cl	1.05	-0.3	0.968	71-119
TCO <sub>2</sub>	1.00	0.3	0.945	10.6-41.5
<b>Urine **</b>				
Na	0.91	5	0.997	20-178
K	0.93	0.2	0.998	9-98
Cl	1.03	2.0	0.979	38-323

\* n = 270; 149 serum and 121 plasma

\*\* n = Na, 100; K, 95; Cl, 105

SYNCHRON CX® is a registered trademark of Beckman Instruments, Brea, CA 92621

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Date