JAN 3 0 2004

510(k) Summary
for Mission Diagnostic BUN Reagent
for Beckman Synchron CX® & CX® Delta Systems

1. **Submitter's Name & Address**

Mission Diagnostics
331 Fiske St
Holliston MA 01746
FAX: 508-429-0452

Contact Person:
Linda Stundtner
QA/RA Manager
508-429-0450

Establishment Registration Number: 3003656721

Date of Preparation: Jan 19, 2004

2. **Identification of the Device:**

Proprietary/Trade name:	BUN Reagent for Beckman Synchron CX & Delta Instrument
Common or usual name	BUN Reagent
Classification name:	Urea Nitrogen test system
Device Classification	II
Regulation Number:	21 CFR § 862.1345
Panel:	Chemistry (75)
Product Code:	CGA

- Mission manufactures reagents intended to serve as direct replacements to like named products manufactured by Original Equipment Manufactures (OEM)

3. **Predicate Device:**

- Mission claims substantial equivalence to the OEM Reagent listed below:

Substantial Equivalence Table of Product PN & Trade Names

Mission Product		OEM Equivalent	
BK-443350D	BUN Reagent	443350	BUN Reagent

- The predicate reagent, Beckman PN 443350, is encompassed in the 510(k)'s K942676 & K864236 cleared 11/02/1994 & 12/31/1986 respectively.

4. **Device Description:**

- Urea nitrogen concentration is determined by an enzymatic conductivity method employing a Beckman Conductivity Electrode. Electronic circuits determine the rate of increase in conductivity, which is directly proportional to the concentration of BUN in the sample.

Intended Use:

- Mission BUN Reagent is intended for the quantitative determination of urea nitrogen in serum, plasma, and urine on Beckman Synchron CX & Delta Analyzers.

  - BUN measurements are used in the diagnosis and treatment of certain renal and metabolic diseases.

- The original equipment manufacturer (OEM) of the instruments and the predicate reagents which are necessary for the continued operation and use of the instruments.

- Mission uses a similar composition, description and packaging as that used by the OEM in its products, as shown in the packaging section of this submission.

5. Performance Characteristics:

Precision and correlation data are collected per:

- SOP23-01-02 Performance Study Protocol for 510(k) Submission

Precison and Correlation are summarized below:

Precision data was collected following the guidelines of NCCLS Guideline EP5-A

- Samples were run for 20 days, 2 runs per day, 2 observations per run on an instrument operated according to the manufacturers instructions. The following data was obtained:

	N	Test Mean mg/dL	S_{wr} within run sd	% CV	S_T Total sd	%CV
Serum Control 1	80	13	0.7	5.5	0.7	5.8
Serum Control 2	80	48	1.3	2.7	3.1	6.5
Urine Control 1	80	58	1.2	2.1	1.9	3.3
Urine Control 2	80	63	1.9	2.9	2.6	4.0

Method Comparison of Mission BUN Reagent to Beckman Reagent following the guidelines of NCCLS Guideline EP9-A2 was conducted.

Serum samples were spiked or diluted and run in triplicate and tested with each reagent, Mission BUN Reagent and Beckman BUN Reagent in separate calibrated runs. Recoveries of individual observations were compared by least squares regression. The following statistics were obtained:

Mission = 0.892 x Beckman + 1.22
Range = 4 to 87 mg/dL; $r^2 = 0.997$; df = 65; n = 66; $S_{(y.x)} = 1.30$ mg/dL

Urine controls were spiked or diluted and run in triplicate and tested with each reagent, Mission BUN Reagent and Beckman BUN Reagent in separate calibrated runs. Recoveries of individual observations were compared by least squares regression. The following statistics were obtained:

Mission = 0.923 x Beckman + 1.054
Range = 4 to 100 mg/dL; $r^2 = 0.996$; df = 41; n = 40; $S_{(y.x)} = 1.70$ mg/dL

Recovery to Expected Values was evaluated for each matrix; serum & urine. Dilutions of the respective matrices were made and measured with Mission and Beckman reagent.

- Pooled Serum was spiked to an expected value of 200 mg/dL by adding urea gravimetrically. Dilutions were made using the spiked serum, serum, and/or Human serum albumin (HmSA).
- Urine recovery samples were made by mixing Urine Control 2 (expected value = 300 mg/dL), Urine Control 1 (expected value = 135 mg/dL), and/or Normal saline.

% Recovery = (Measured/expected) x100 was calculated for both Mission and Beckman. Mission and Beckman exhibited similar recoveries across the range of values in all matrices. See table below:

Matrix	Range of Conc. Expected, mg/dL	Reagent	Range of average % Recovery	Overall Mean Recovery
Serum	81.0 – 7.5 mg/dL	Mission	82 – 106	97
		Beckman	94 – 111	105
Urine	100 – 10.5 mg/dL	Mission	85.7 – 103.8	97.6
		Beckman	93.3 – 110	101.2

Functional sensitivity was evaluated on dilutions of serum samples made from a starting serum of an approximately concentration of 13.7 mg/dL; and dilutions of 1:3, 1:5.1:11 and a zero. Dilutions were tested as 4 samples per run over 5 calibrated runs.

- The lowest level where the % CV was less than 20% was with the dilution at an expected value of 3 mg/dL BUN which measured/recovered as:
  - 3 mg/dL with Mission reagent
  - 5 mg/dL with Beckman reagent.

The CX Delta reports BUN values to the whole number.

		Mission Reagent				Beckman Reagent			
Dilution	Expected value mg/dL	Mean	sd	N	%CV	Mean	sd	N	%CV
1	13.7	14.1	0.60	20	4.3	15.1	1.52	20	10.1
2	4.6	5.1	0.22	20	4.4	6.4	0.50	20	7.9
3	2.7	**3.1**	0.22	20	**7.3**	**4.6**	0.50	20	**10.9**
4	0.7	1.0	0.56	20	56.2	3.0	0.97	20	32.4
5	0.0	0.5	0.71	2	141.4	NA	NA	0	NA

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Linda M. Stundtner
QA/RA Manager
Diamond Diagnostics
Mission Diagnostics Division
331 Fiske St.
Holliston. MA 01746

JAN 3 0 2004

Re: k033056
Trade/Device Name: Mission Diagnostic BUN Reagent for Beckman Synchron CX® & CX® Delta Systems
Regulation Number: 21 CFR 862.1770
Regulation Name: Urea nitrogen test system
Regulatory Class: Class II
Product Code: CDS
Dated: December 22, 2003
Received: December 24, 2003

Dear Ms. Stundtner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K033056

Device Name Mission Diagnostic BUN Reagent for Beckman Synchron CX® & CX® Delta Systems

Indications For Use:

- Mission BUN Reagent is intended for in vitro diagnostic use for the quantitative determination of blood urea nitrogen (BUN) in serum, plasma, and urine on Beckman Synchron CX® & CX® Delta Analyzers.
- BUN measurements are useful in the diagnosis and treatment of certain renal and metabolic diseases

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C. Benson for Jean Cooper, DVM
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K033056