K050119

MAY - 6 2005

510(k) Summary
Beckman Coulter PARAGON CZE® 2000
Urine Protein Electrophoresis (UPE) Kit and
Urine Immunofixation By Subtraction (U-IFE/s) Kit

1.0 Submitted By:

Kim Walker
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2.0 Date Submitted:

January 14, 2005

3.0 Device Name(s):

3.1 Proprietary Names

PARAGON CZE® 2000 Urine Protein Electrophoresis (UPE) Kit

PARAGON CZE® 2000 Urine Immunofixation by Subtraction (U-IFE/s) Electrophoresis Kit

3.2 Classification Name

UPE & U-IFE/s - Bence-Jones proteins immunological test (21 CFR § 866.5150)

4.0 Predicate Devices:

Candidate	Predicate	Manufacturer	Docket Number
PARAGON CZE 2000 UPE Kit	PARAGON SPE Kit	Beckman Coulter, Inc.	K802592
PARAGON CZE 2000 U-IFE/s Kit	PARAGON IFE Kit	Beckman Coulter, Inc.	K823884

5.0 Description:

The PARAGON CZE® 2000 UPE and U-IFE/s kits are designed for optimal performance on the PARAGON CZE® 2000. The UPE kits contain one Segment package containing 20 Segments, five Desalting Column packages with 4 columns per package, and four 500 mL Desalting Reagent bottles. The U-IFE/s kits contain two Segment packages containing 10 Segments, one Desalting Column package with 4 columns per package, and one 500 mL Desalting Reagent bottle.

6.0 Intended Use:

The PARAGON CZE® 2000 Urine Protein Electrophoresis (UPE) Kit is intended for use with the Paragon CZE 2000 Capillary Electrophoresis System for the electrophoretic separation of proteins in human urine.

The PARAGON CZE® 2000 Urine Immunofixation by Subtraction (U-IFE/s) Electrophoresis Kit is intended for use with the Paragon CZE 2000 Capillary Electrophoresis System for the immunologic identification of monoclonal components in human urine.

7.0 Comparison to Predicate(s):

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

Similarities to the Predicate

Kit	Aspect/Characteristic	Comments
UPE Kit	Basic Technology (Electrophoretic Migration)	Same as Beckman Paragon SPE Kit
	Urine Sample Type	
	Shelf Life Stability	
	Specificity	
	Qualitative Results	
U-IFE/s Kit	Basic Technology (Electrophoretic Migration with Immunofixation)	Same as Beckman Paragon IFE Kit
	Urine Sample Type	
	Qualitative Results	
	Shelf Life Stability	
	Antisera Storage	
	Antisera Specificity	

Differences From The Predicate

Kit	Aspect/ Characteristic	Comments
UPE Kit	Intended Use	The Paragon CZE 2000 Urine Protein Electrophoresis (UPE) Kit is intended for use with the Paragon CZE 2000 Capillary Electrophoresis System for the electrophoretic separation of proteins in human urine. The Paragon Serum Protein Electrophoresis (SPE) Kit is intended for the electrophoretic separation of proteins in human serum, cerebrospinal fluid, and urine.
	Sample Preparation	**UPE** – No concentration required for urine samples with a total protein of 20-4800 mg/dL. Must desalt before running sample on CZE. Any samples <20 mg/dL must be concentrated and >4800 mg/dL must be diluted. **SPE** – Concentration required for all urine samples <700 mg/dL total protein.
	Interferences	**UPE**- Any materials that would absorb at 214 nm and not removed by desalting. Hemoglobin co-migrates with transferrin. **SPE** – Lipemic and hemolyzed samples.
	Lowest Detectible Limit	**UPE** – 0.5-2.0 mg/dL of Kappa and Lambda Bence Jones Proteins were visible when no other co-migrating proteins were present. **SPE** – No claims made.
	Methodology	**UPE** – Capillary Electrophoresis **SPE** – Gel Electrophoresis
	Sample Size	**UPE** - 0.5 mL Desalted Urine **SPE** - 3-5 uL Concentrated or Neat Urine
	Storage Temperature	**UPE** – 2 - 30˚C **SPE** – 18 - 26˚C
	Analytic Range	**UPE** – Single Protein Component 0.5 - 2.0 mg/dL to 4600 mg/dL & Total Protein 0.02 – 4.80 g/dL **SPE** – Total Protein >700 mg/dL

Kit	Aspect/ Characteristic	Comments
U-IFE/s Kit	Intended Use	The Paragon CZE 2000 Urine Immunofixation by Subtraction (U-IFE/s) Electrophoresis Kit is intended for use with the Paragon CZE 2000 Capillary Electrophoresis System for the immunologic identification of monoclonal components in human urine. The Paragon Immunofixation Electrophoresis (IFE) Kit is for the immunologic identification of proteins in human serum, cerebrospinal fluid, and urine.
	Sample Preparation	**U-IFE/s** – No concentration required for urine samples w/ monoclonal components of 5 - 300 mg/dL. Must desalt before running sample on CZE. Any samples <5 mg/dL of monoclonal components or <2.5 – 10.0 mg/dL of monoclonal components must be concentrated & >300 mg/dL of monoclonal components must be diluted. **IFE** – Concentration required for all urine samples <100 mg/dL total protein for the detection of Bence-Jones Proteins. Concentration up to 800 – 1000 mg/dL should be conducted on all urine samples for the detection of immunoglobulins.
	Interferences	**U-IFE/s**- Any materials that would absorb at 214 nm and not removed by desalting. Hemoglobin co-migrates w/ transferrin. **IFE** – Fibrinogen containing, IgM Immune complex containing & hemolyzed samples.
	Lowest Detectible Limit	**U-IFE/s** – 2.5-5.0 mg/dL of Lambda & 5.0-10.0 mg/dL of Kappa Bence-Jones proteins were visible when no other co-migrating proteins were present. **IFE** – No claims made.
	Methodology	**U-IFE/s** – Capillary Electrophoresis **IFE** – Gel Electrophoresis
	Sample Size	**U-IFE/s** – 300-700 µL Desalted Urine depending on the dilution used **IFE** - 3-5 uL Concentrated or Neat Urine
	Storage Temperature other than Antisera	**U-IFE/s** – 2 - 30˚C **IFE** – 18 - 26˚C
	Analytic Range	**U-IFE/s** – 2.5 - 5.0 mg/dL to 300 mg/dL Lambda & 5.0 – 10.0 mg/dL to 300 mg/dL Kappa **IFE** – Total Protein >100 mg/dL for detection of Bence-Jones Proteins. Total Protein >800-1000 mg/dL for detection of immunoglobulins.

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, linearity/sensitivity, and precision/ reproducibility experiments.

Method Comparison Study Results

Instrument	Agreement	Partial Agreement	Disagreement	n	Comparison Method
PARAGON CZE 2000 – UPE Kit	95	4	1	100	PARAGON Gel Electrophoresis – SPE Kit

Instrument	Full Agreement	Disagreement	n	Comparison Method
PARAGON CZE 2000 – U-IFE/s Kit	76 (92.7%)	6 (7.3%)	82	PARAGON Gel Electrophoresis – IFE Kit

UPE Imprecision Results

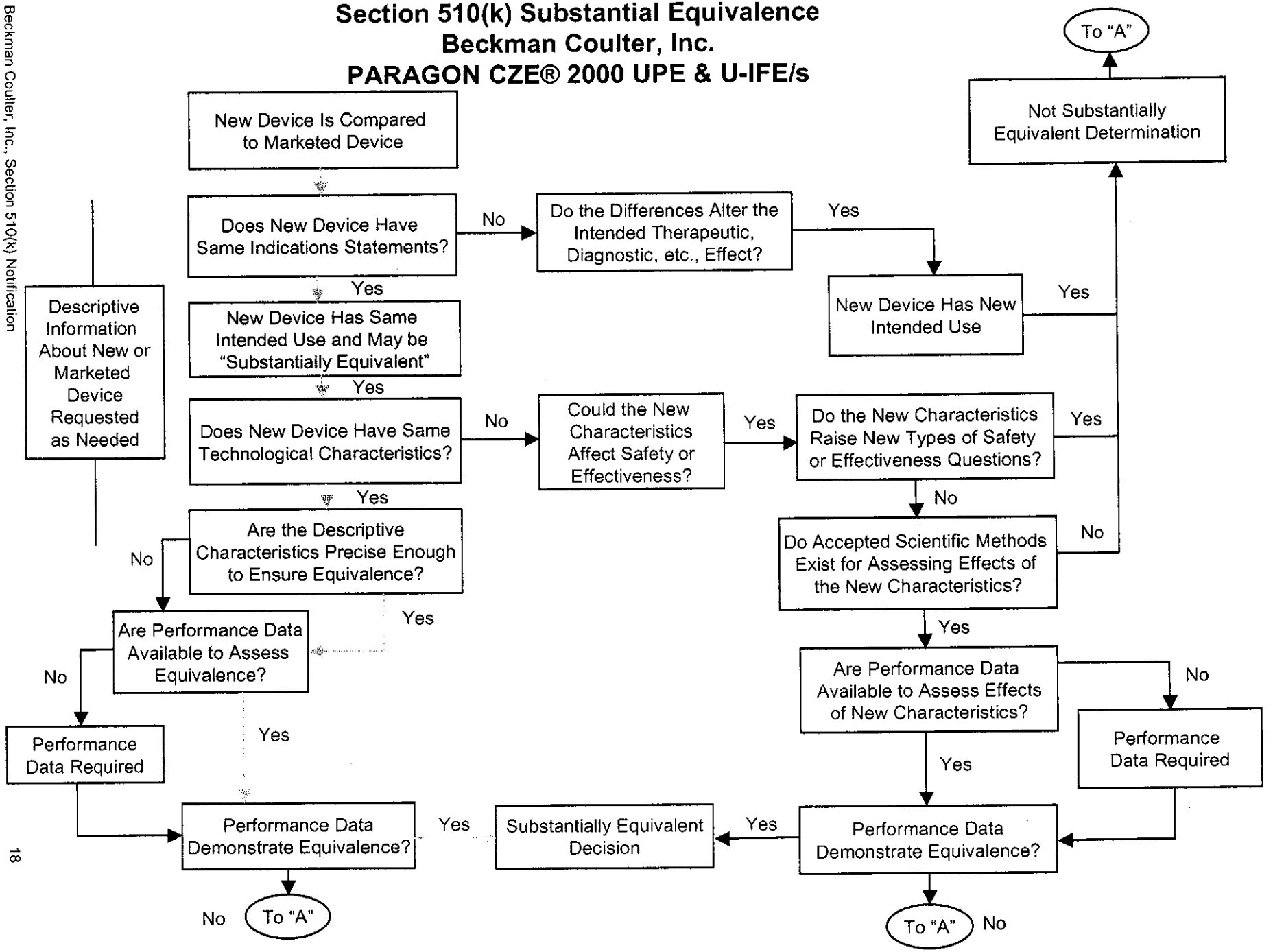
Type of Imprecision	Sample	Fraction	Mean (Relative %)	S.D. (Relative %)	% C.V.	N
Within-Run Imprecision						
System Reproducibility	Urine Pool	Albumin	55.1	1.38	2.5	21
		BJP	13.2	0.93	7.1	21
Desalting Reproducibility	Urine Pool	Albumin	54.8	1.65	3.0	21
		BJP	13.5	0.71	5.3	21
Total Imprecision						
Total (EP 10-A)	Urine Level 1	Albumin	28.8	0.7	2.5	15
		BJP	13.4	0.8	5.9	15
	Urine Level 2	Albumin	60.8	1.3	2.2	15
		BJP	6.5	0.8	12.7	15
	Urine Level 3	Albumin	9.2	0.8	9.2	15
		BJP	72.1	1.5	2.0	15

U-IFE/s Reproducibility Results

The electropherograms were visually inspected to ensure that at least 80% were within agreement. No observable difference in morphology or subtraction was seen between the segments for each of the samples tested. BJP subtraction with kappa and lambda was as expected. Reproducibility meets the 80% specification for visual agreement for the replicate segments.

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.

Section 510(k) Substantial Equivalence
Beckman Coulter, Inc.
PARAGON CZE® 2000 UPE & U-IFE/s



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY - 6 2005

Ms. Kim Walker, RAC
Regulatory Affairs Manager
Beckman Coulter, Inc.
200 S. Kraemer Boulevard
M/S W-515
Brea, California 92822-8000

Re: k050119
Trade/Device Name: PARAGON CZE® 2000 Urine Protein Electrophoresis (UPE) Kit and Urine Immunofixation by Subtraction (U-IFE/s) Kit
Regulation Number: 21 CFR § 866.5150
Regulation Name: Bence-Jones proteins immunological test
Regulatory Class: II
Product Code: JKM, CFF, DFH, DEH
Dated: March 30, 2005
Received: March 31, 2005

Dear Ms Walker:

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 (240) 276-0484. 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/industry/support/index.html

Sincerely yours,

Robert L. Becker, Jr., MD, Ph.D
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050119

Device Name: **PARAGON CZE® 2000 Urine Protein Electrophoresis (UPE) Kit and Urine Immunofixation By Subtraction (U-IFE/s) Kit**

Indications for Use:

The PARAGON CZE® 2000 Urine Protein Electrophoresis (UPE) Kit is intended for use with the Paragon CZE 2000 Capillary Electrophoresis System for the electrophoretic separation of proteins in human urine.

The PARAGON CZE® 2000 Urine Immunofixation by Subtraction (U-IFE/s) Electrophoresis Kit is intended for use with the Paragon CZE 2000 Capillary Electrophoresis System for the immunologic identification of monoclonal components in human urine.

Prescription Use ✓ 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)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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