K011596

JUL 1 7 2001

JAS DIAGNOSTICS: 510(K) NOTIFICATION

510(K) SUMMARY

Submitter	Name: Attn: David Johnston JAS Diagnostics, Inc. 7220 N.W. 58th Street Miami, FL 33166 Phone: 305 418-2320 Fax: 305 418-2321 Email: D.Johnston@JASDiagnostics.com
Device Name:	Trade Name: JAS Urea Nitrogen (BUN) Liquid Reagent Common Name: Urea Nitrogen Reagent Classification Name: 21 CFR 862.1770
Predicate Devices:	-Roche Diagnostics BUN (Urea Nitrogen) Reagent for the Cobas Mira analyzers -Pointe Scientific Urea Nitrogen (BUN) Reagent (generic)
Device Description:	This Reagent is intended for the in vitro quantitative determination of urea nitrogen in human serum.
Summary of the Similarities to the Predicate Devices:	Intended Use: All devices are intended for the detection of urea nitrogen in human serum on automated chemistry analyzers. Results Interpretation: Correlation studies on human serum demonstrated acceptable result comparisons between these methods, which all use similar normal ranges.
Discussion and Conclusion:	The JAS Urea Nitrogen (BUN) Liquid Reagent's intended use is identical to predicate Devices and it's performance acceptable on the automated chemistry analyzers tested. The JAS Urea Nitrogen (BUN) Liquid Reagent is therefore substantially equivalent to FDA registered Urea Nitrogen (BUN) Reagents currently in the market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 17 2001

Mr. David Johnston
Technical Director
JAS Diagnostics, Inc.
7220 NW 58th Street
Miami, FL 33166

Re: 510(K) Number: K011596
Trade/Device Name: Urea Nitrogen (BUN) Reagent
Regulation Number: 862.1770
Regulatory Class: II
Product Code: CDQ
Dated: April 26, 2001
Received: May 24, 2001

Dear Mr. Johnston:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): ___N/A_____

K011596

Device Name: __Urea Nitrogen (BUN) REAGENT__

Indications for Use:

Intended for the In Vitro, quantitative determination of urea nitrogen (BUN) in human serum on automated chemistry analyzers.

Urea Nitrogen measurements obtained by this device are used in the diagnosis and treatment of certain renal and metabolic diseases.

Ann Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K011596

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use ___

(Per 21 CFR 801.109)

(Optional Format 1-2-96)