

K981295

OCT 1 1998

## 510(k) Summary

**Submitter's Name/Address**

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1920 Hurd Drive  
Irving, Texas 75038

**Contact Person**

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Section Manager MS 1-8  
ADD Regulatory Affairs  
(972) 518-7861  
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**Date of Preparation of this Summary:**

September 29, 1998

**Device Trade or Proprietary Name:**

UPro

**Device Common/Usual Name or Classification Name:** Urine/CSF Protein**Classification Number/Class:**

75JGQ/Class I

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.

The assigned 510(k) number is: K981295.

**Test Description:**

Urine/CSF Protein is an *in vitro* diagnostic assay for the quantitative determination of protein in human urine or cerebrospinal fluid (CSF) on the ALCYON™ Analyzer. The Urine/CSF Protein assay is a clinical chemistry assay using a turbidimetric procedure in which benzethonium chloride is used as the protein denaturing agent. Proteins present in the urine or CSF are denatured by benzethonium chloride resulting in the formation of a fine suspension which is quantitated turbidimetrically at 405 nm. The reagent has been modified to overcome the problem of high concentration (Hook) effect, where very high concentrations of protein in urine can cause an apparent zero or low reading.

**Substantial Equivalence:**

The Urine/CSF Protein assay is substantially equivalent to the Boehringer Mannheim® Urinary/CSF Protein assay on the Hitachi® 717 Analyzer (K913615).

Both assays yield similar Performance Characteristics.

**Similarities:**

- Both assays are *in vitro* clinical chemistry methods.
- Both assays can be used for the quantitative determination of protein in urine or cerebrospinal fluid.
- Both assays yield similar clinical results.

**Intended Use:**

The Urine/CSF Protein assay is used for the quantitative determination of protein in human urine or cerebrospinal fluid (CSF).

**Performance Characteristics:**

Comparative performance studies were conducted using the ALCYON™ Analyzer. The Urine/CSF Protein assay method comparison yielded acceptable correlation with the Boehringer Mannheim Urinary/CSF Protein assay on the Hitachi 717 Analyzer. For the urine application, the correlation coefficient = 0.995, slope = 0.943, and Y-intercept = 5.146 mg/dL. For the CSF application, the correlation coefficient = 0.981, slope = 0.995, and Y-intercept = 1.184 mg/dL. Precision studies were conducted using the Urine/CSF Protein assay. Within-run, between-run, and between-day studies were performed using two levels of control material. The total %CV for Level 1/Panel 131 is 5.1% and Level 2/Panel 132 is 4.5% for the urine application. The total %CV for Level 1/Panel 601 is 2.6% and Level 2/Panel 602 is 2.1% for the CSF application. The Urine/CSF Protein assay is linear from 10 to 200 mg/dL. The limit of quantitation (sensitivity) for the Urine/CSF Protein assay is 10 mg/dL. The functional sensitivity was based on the lowest calibrator (standard) value used in the determination of the Urine/CSF Protein Linearity (standards ranged

from 10 to 200 mg/dL). These data demonstrate that the performance of the Urine/CSF Protein assay is substantially equivalent to the performance of the Boehringer Mannheim Urinary/CSF Protein assay on the Hitachi 717 Analyzer.

**Conclusion:**

The Urine/CSF Protein assay is substantially equivalent to the Boehringer Mannheim Urinary/CSF Protein assay on the Hitachi 717 Analyzer as demonstrated by results obtained in the studies.



Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

OCT 1 1998

Mark Littlefield  
• Section Manager, Regulatory Affairs  
Abbott Laboratories  
1920 Hurd Drive  
Irving, Texas 75038

Re: K981295  
Alcyon Urine/CSF Protein  
Regulatory Class: I  
Product Code: JGQ  
Dated: August 13, 1998  
Received: August 14, 1998

Dear Mr. Littlefield:

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 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.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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" (21 CFR 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/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

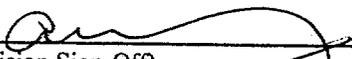
510(k) Number (if known): R981295

Device Name: Urine/CSF Protein

Indications For Use:

The Urine/CSF Protein assay is used for the quantitative determination of protein in human urine or cerebrospinal fluid (CSF) on the ALCYON™ Analyzer. Identification of urinary protein is used in the diagnosis and treatment of disease conditions such as renal or heart diseases or thyroid disorders, which are characterized by proteinuria or albuminuria. CSF protein measurements are used in the diagnosis and treatment of conditions such as meningitis, brain tumors, and infections of the central nervous system.

*Prescription use*  
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(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number R981295

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)