# 510(k) Summary

**Submitter's Name/Address**
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**Contact Person**
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**Date of Preparation of this Summary:** May 12, 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: _____.

**Test Description:**

Urine/CSF Protein is an *in vitro* diagnostic assay for the quantitative determination of protein in human urine or cerebrospinal fluid (CSF). 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.

Differences:

- There is a difference in the wavelength of which the two methods are read.

**Intended Use:**

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

**Performance Characteristics:**

Comparative performance studies were conducted using the AEROSET™ 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 = 0.992, slope = 1.065, and Y-intercept = -0.264 mg/dL. For the CSF application, the correlation coefficient = 0.9965, slope = 0.985, and Y-intercept = 5.762 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. For the urine application, the total %CV for Level 1/Panel 201 is 4.8% and Level 2/Panel 202 is 2.5%. For the CSF application, the total %CV for Level 1/Panel 301 is 2.4% and Level 2/Panel 302 is 1.5%. The Urine/CSF Protein assay is linear up

to 200 mg/dL. The limit of quantitation (sensitivity) for the Urine/CSF Protein assay is 4.8 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 21 1998

Mark Littlefield
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Re: K981682
UPro for Aeroset
Regulatory Class: I
Product Code: JGQ
Dated: July 17, 1998
Received: July 21, 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): K98168.2

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 AEROSET System. 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.

Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K98168.2

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)