K970277

510(k) SUMMARY

Astoria-Pacific Uridyltransferase 50-Hour Reagent Kit

510(K) SUMMARY

DEC 11 1997

IDENTIFICATION

Submitter's Name: Raymond L. Pavitt, President
Astoria-Pacific, Inc.
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Contact Person: Lester B. Garrison, Diagnostics Manager

Date Summary Prepared: August 4, 1997

NAME OF DEVICE

Proprietary Name: Uridyltransferase (GALT) 50-Hour Reagent Kit
Common Name: Uridyltransferase (GALT) Test System
Classification Name: 862.1315 Galactose-1-Phosphate Uridyltransferase Test System

LEGALLY MARKETED DEVICE EQUIVALENT TO PROPOSED DEVICE

The Uridyltransferase 50-Hour Reagent Kit is substantially equivalent to a legally marketed predicate device, Sigma Galactose-1-Phosphate Uridyltransferase (Gal-PUT) Deficiency Screen.

DESCRIPTION OF PROPOSED DEVICE

The proposed device, Uridyltransferase 50-Hour Reagent Kit, is a set of reagents to be used with the API™ 300 SPOTCHECK® Analyzer or the RFA-300 System for the quantitative determination of the enzyme galactose-1-phosphate uridyltransferase (UT) in whole blood saturated filter paper disks. The amount of uridyltransferase activity is determined by measuring the fluorescent compound produced in the reaction of UT with galactose and UDP Glucose, followed by NADP reduction at 37°C. The excitation wavelength of the reaction product is 450 nm, and it's emission is measured at 550 nm. The method is specific for uridyltransferase.

The method is designed for mass screening, with enough reagents in each 50-Hour Reagent Kit for 1 week plus start-up (50 hours total) of run time. It is packaged to reduce storage space and to require a minimum of time to prepare. Each component is packaged with the correct weight to prepare the required volume of reagent. The standard is in a concentrated form, to permit easy dilution to prepare a standard curve. The materials provided and their components are listed below.

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Astoria-Pacific **Uridyltransferase 50-Hour Reagent Kit**

REAGENTS

DESCRIPTION	Component	Concentration	Quantity
GALT Extraction Buffer	Succinate Buffer pH 5.2	0.8 mM	1 Liter
Recipient Diluent	Tris Buffer, pH 7.8 Triton X-100	100 mM 0.5 mL/L	1 Liter
GALT Buffer Part A.	Tris Buffer, pH 7.8 NADP Dithiothreitol	100 mM 1.3 mM 1.0 mM	5 x 150 mL
GALT Buffer Part B.	Magnesium EDTA Triton X-100	0.6 mM 0.1 mM 0.5 mL/L	
PGluM Substrate Reagent	Glu-1-Phosphate	10. mM	10 mL
GALT Substrate Reagent	Gal-1-Phosphate UDPG G6PDH Yeast PGluM Rabbit Muscle	4.3 mM 0.5 mM 1.6 KU/L 0.8 KU/L	5 x 60 mL
NADH Stock Standard	TEA Buffer, pH 9.0 NADH	50 mM 50 µM	2 x 50 mL

INTENDED USE

This Astoria-Pacific SPOTCHECK® Uridyltransferase 50-Hour Reagent Kit is for the qualitative determination of galactose-1-phosphate uridyltransferase, EC 2.7.7.12 (GALT) activity in whole blood saturated filter paper disks (S&S 903 filter paper or equivalent), using the API™ 300 SPOTCHECK® Analyzer or the RFA-300 System. Measurements of galactose-1-phosphate uridyltransferase are used in the diagnosis and treatment of the hereditary disease galactosemia. This method is intended for in vitro diagnostic use as an aid in screening for decreased levels of GALT activity in infants. This method is not for monitoring purposes.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS OF DEVICE COMPARED TO PREDICATE DEVICE

Similarities with Predicate Device

The Astoria-Pacific SPOTCHECK® Uridyltransferase 50-Hour Reagent Kit is similar to a predicate device, Sigma Galactose-1-Phosphate Uridyltransferase (Gal-PUT) Deficiency Screen, having the same technological characteristics and intended use. Both are diagnostic reagent kits to be used for the qualitative, fluorometric determination of the enzyme uridyltransferase in blood; both have the same chemical principles and reaction mechanism.

The reactants and reactions are the same. Both devices use the same incubation temperature and a similar incubation time.

Differences from Predicate Device

While the method and reagents are similar for the proposed and predicate devices, there are minor differences. The Sigma device uses G6PD and PGluM from the sample for the reactions. The proposed device adds these enzymes to the reagent. The Sigma device requires manual reading of fluorescence; the API™ 300 SPOTCHECK® Analyzer reads the fluorescence automatically.

There are also differences in the wavelengths of the excitation and emission filters. The proposed device designates 450 nm and 550 nm for the excitation and emission wavelengths, respectively; the Sigma device uses a broad band UV lamp for excitation and visual fluorometry for reading the emitted fluorescence. Because there is a broad bandpass of about 40 nm for the filters on the API™ 300 SPOTCHECK® Analyzer and the emitted fluorescent light is broad spectrum, this difference is not consequential.

The API Uridyltransferase 50-Hour Reagent Kit contains a NADH standard for comparrision of the fluorescence readings.

The Sigma Gal-PUT Deficiency Screen test requires the user to prepare all reagents; in the Astoria-Pacific SPOTCHECK® Uridyltransferase 50-Hour Reagent Kit, the reagents are either pre-made or pre-weighed.

The minor differences between the Astoria-Pacific SPOTCHECK® Uridyltransferase 50-Hour Reagent Kit and the Sigma Gal-PUT Deficiency Screen raise no questions of safety or efficacy.

BRIEF DISCUSSION OF NONCLINICAL TESTS

Because there is such a strong similarity between the Astoria-Pacific SPOTCHECK® Uridyltransferase 50-Hour Reagent Kit and the Sigma Gal-PUT Deficiency Screen, no nonclinical testing has been performed to demonstrate substantial equivalence.

BRIEF DISCUSSION OF CLINICAL TESTS

Clinical testing was performed on whole blood saturated filter paper disks. These tests include 27 specimens analyzed, of which 20 were normal neonatal blood samples and 7 were deficient samples from juveniles and adults. Results correlated well, as there were no false positives and no false negatives among any of the samples tested.

CONCLUSIONS DRAWN FROM THE NONCLINICAL AND CLINICAL TESTS

The clinical tests demonstrate that the proposed device, the Astoria-Pacific SPOTCHECK® Uridyltransferase 50-Hour Reagent Kit, is safe, effective and performs as well as a predicate device, as evidenced by the correlation of results obtained from clinical studies.

OTHER INFORMATION

No other information has been requested by FDA at this time.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 11 1997

Lester B. Garrison
Submission Correspondent
Astoria-Pacific, Inc.
14600 S.E. 82nd Drive
P.O. Box 830
Clackamas, Oregon 97015

Re: K970277
Uridyltransferase Test System
Regulatory Class: II
Product Code: KQP
Dated: November 5, 1997
Received: November 6, 1997

Dear Mr. Garrison:

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): K970277

Device Name: UridylTRANSFERASE 50-Hour REAGENT Kit

Indications For Use:

October 8, 1997

Astoria-Pacific, Inc.

Statement of Indications for use:

This Astoria-Pacific SPOTCHECK® Uridyltransferase 50-Hour Reagent Kit is for the qualitative determination of galactose-1-phosphate uridyltransferase (EC 2.7.7.12) (GALT) activity in whole blood saturated filter paper disks, S&S 903 filter paper or equivalent, using the API ™ 300 SPOTCHECK® Analyzer or the RFA-300 System. Measurements of galactose-1-phosphate uridyltransferase are used in the diagnosis and treatment of the hereditary disease galactosemia. This method is intended for in vitro diagnostic use as an aid in screening for decreased levels of GALT enzyme activity in infants. This method is not for monitoring purposes.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K970277

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use____

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number