

MAR 19 1998

510(k) Summary

IDENTIFICATION

Submitter's Name: Raymond L. Pavitt, President
Astoria-Pacific, Inc.

Address: 14600 SE 82nd Drive
Clackamas, OR 97015-0830, USA

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Contact Person: Lester B. Garrison, Diagnostics Manager

Date Summary Prepared: February 3, 1998

NAME OF DEVICE

Proprietary Name: Tyrosine 50-Hour Reagent Kit

Common Name: Free Tyrosine Test System

Classification Name: 1-Nitroso-2-naphthol (Fluorometric), Free Tyrosine

LEGALLY MARKETED DEVICE EQUIVALENT TO PROPOSED DEVICE

The Tyrosine 50-Hour Reagent Kit is substantially equivalent to a legally marketed predicate device, Technicon Tyrosine test.

DESCRIPTION OF PROPOSED DEVICE

The proposed device, Tyrosine 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 amino acid tyrosine (Tyr) in whole blood saturated filter paper disks. The amount of Tyr is determined by measuring the fluorescent compound produced in the reaction of tyrosine with 1-nitroso-2-naphthol, catalyzed by nitrous acid at 80°C. The excitation wavelength of the product is 450 nm and emission is measured at 550 nm. The method is specific for *para*-substituted phenolic compounds. Excess 1-nitroso-2-naphthol is removed from the reaction mixture by reduction with sodium *m*-bisulfite.

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.

<u>Reagent</u>	<u>Active Component(s)</u>	<u>Concentration</u>	<u>Volume</u>
Extraction Buffer	Succinate Buffer	6.0 mM	1000 mL
Saline Diluent, 0.9%	Sodium Chloride Triton X-100	154. mM 0.05%	600 mL
Complex Reagent	1-Nitroso-2-Naphthol DMSO	1.5 mM 3.5 M	500 mL
Sodium Nitrite, 2.5%	Sodium Nitrite	0.36 M	10 mL
Nitrous Acid	Nitric Acid, 10% Sodium Nitrite, 2.5%	50 mL 0.25 mL —Added before use	50 mL
Sodium Metabisulfite	Sodium Metabisulfite	0.26 M	500 mL
Tyrosine Stock Standard, 10 mg/dL	L-Tyrosine Hydrochloric Acid	0.55 mM 6.0 mM	50 mL

INTENDED USE

This method is for the quantitative determination of the amino acid tyrosine in whole blood saturated filter paper disks using the API™ 300 SPOTCHECK® Analyzer or the RFA 300 System. Measurements obtained by this device are used in the diagnosis and treatment of diseases such as congenital tyrosinemia, a disease that can cause liver/kidney disorders.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS OF DEVICE COMPARED TO PREDICATE DEVICE

Similarities with Predicate Device

The Astoria-Pacific SPOTCHECK® Tyrosine 50-Hour Reagent Kit is similar to the predicate device, Technicon Tyrosine test, having the same technological characteristics and intended use. Both are diagnostic reagent kits to be used for the quantitative, automated, fluorometric determination of the amino acid tyrosine in blood; both have the same chemical principles and reaction mechanism.

The reagents are identical, and there are no new reagents. The proposed device uses approximately the same temperatures, time and ratios of reagents as the predicate device.

Differences from Predicate Device

While the method and reagents are identical for the proposed and predicate devices, there are minor variations in the surfactants. The Technicon device uses Brij-35, while the proposed device uses Triton X-100, as it is available in a purified grade. In addition, the sample for the proposed device is whole blood spotted on filter paper and extracted with a

buffer; the sample for the predicate device is not specified. The proposed device is designed for a sampling rate of 90 per hour vs. 50 per hour for the predicate device.

There are also slight differences in the temperature of the assay and the wavelengths of the excitation and emission filters. The temperature of the assay, which affects the level of fluorescence produced, is 80°C for the 50-Hour Reagent Kit and 90°C for the Technicon Tyrosine test; temperatures from 55°C to 90°C are cited in the literature for this reaction. The Proposed device designates 450 nm and 550 nm for the excitation and emission wavelengths, respectively; the predicate device uses 440 nm and 540 nm, respectively. Because there is a broad bandpass of about 40 nm for the filters, and the emitted fluorescent light is broad spectrum, this difference is not consequential.

Other differences include concentration range (0-200 mg/L for Astoria-Pacific vs. 0-2 mg/L for Technicon), detection limit and upper limit of the assay. Also, the Technicon Tyrosine test required the user to prepare all reagents; in the 50-Hour Reagent Kit, the reagents are either pre-made or pre-weighed.

The minor differences between the Astoria-Pacific SPOTCHECK® Tyrosine 50-Hour Reagent Kit and the Technicon Tyrosine test raise no questions of safety or efficacy.

BRIEF DISCUSSION OF NONCLINICAL TESTS

Because there is such a strong similarity between the Astoria-Pacific SPOTCHECK® Tyrosine 50-Hour Reagent Kit and the Technicon Tyrosine test, no nonclinical testing has been performed to demonstrate substantial equivalence to the predicate device.

BRIEF DISCUSSION OF CLINICAL TESTS

Clinical testing has been performed on whole blood saturated filter paper disks. These test include 1,096 specimens analyzed by the State of California's Genetic Disease Laboratory, of which 532 were normal neonatal blood samples and 521 were spiked samples. Results correlated well with the expected values for the spiked samples; all normal neonatal blood samples yielded tyrosine values within the normal range. Other testing is described in the product labeling.

CONCLUSIONS DRAWN FROM THE NONCLINICAL AND CLINICAL TESTS

The clinical tests demonstrate that the proposed device, the Astoria-Pacific SPOTCHECK® Tyrosine 50-Hour Reagent Kit, is safe and performs as well as or better than the predicate device.

OTHER INFORMATION

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

End of 510(k) SUMMARY.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 19 1998

Raymond L. Pavitt
President
Astoria-Pacific, Inc.
14600 SE 82nd Drive
Clackamas, Oregon 97015-0830

Re: K970093
Tyrosine 50-Hour Reagent Kit
Regulatory Class: II
Product Code: CDR
Dated: February 4, 1998
Received: February 5, 1998

Dear Mr. Pavitt:

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.

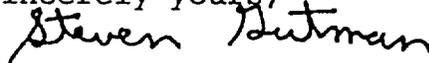
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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 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): K970093

Device Name: Tyrosine 50-Hour Reagent Kit.

Indications For Use:

This method is for the quantitative determination of the amino acid tyrosine in whole blood saturated filter paper disks using the API™ 300 SPOTCHECK® Analyzer or the RFA 300 System. Measurements obtained by this device are used primarily to screen newborns for congenital tyrosinemia, a disease that can cause liver/kidney disorders.

(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)

[Signature]

(Division Sign-Off)
Division of Quality Management
510(k) Number K970093