

**1. Name, Address of Contact Person**

Applicants name and address

Astoria-Pacific, Inc.

FDA Establishment No. 3050015

15130 SE 82nd Drive

Post Office Box 830

Clackamas, OR 97015-0830

Tel 1-503-657-3010

Fax 1-503-655-7367

Charles A. Peterson

CEO

Jason Reynolds

Official Correspondent

**2. Name of the Device**

Product Classification

Regulation Number: 21 CFR 862.1660

510(k) Number: K090940

Classification Panel: Clinical Chemistry

Product Code: JJT

Device Classification: Class I

Product Nomenclature

Common Name: Blood Spot Controls

Classification Name: Quality control material (assayed and unassayed)

Proprietary Name: SPOTCHECK<sup>®</sup> Blood Spot Control

Model Number: Part No. 80-0900P4K, Deficient; Part No. 80-0901P4K, Normal

### **3. Identification of the legally-marketed device for which substantial equivalence is claimed**

The proposed device is substantially equivalent to Bio-Rad Laboratories Quantase Neonatal GALT control set, item 532-6002, intended for use with the MICROPLATE NEONATAL GALT ASSAY kit, item 532-6001 (classification name "fluorescent proc. (qual.), galactose-1-phosphate uridyl transferase"), K990827.

### **4. Description of the Device**

SPOTCHECK Blood Spot Controls

CONTENTS:

Part No. 80-0900P4K, Blood Spot Controls, Deficient; 4 cards

Part No. 80-0901P4K, Blood Spot Controls, Normal; 4 cards

Commercial assays screening for enzyme activity are used to detect inborn errors of metabolism involving Galactose-1-Phosphate Uridyltransferase (GALT) and Biotinidase enzyme deficiencies. The presence of sufficient enzyme activity indicates a negative result for the assay. The lack of enzyme activity, or greatly reduced enzyme activity, indicates a presumptive positive result for the metabolic error and requires follow up and testing.

The controls are prepared with mixtures of human serum and human red blood cells, adjusted to approximately 55% hematocrit. Enzyme activity in the Deficient Control is decreased by heating. Enzyme activity in the Normal Control is supported by the addition of dithioerythritol (DTE). The mixtures are spotted on Whatman 903A filter paper and allowed to air dry at room temperature. The suppliers of serum and red blood cells certify that the materials have been tested using FDA-approved assays and shown to be negative for infectious disease agents.

The SPOTCHECK Blood Spot Controls provide an ongoing indication of the assay performance. The Deficient Control responds below the assay cutoff, and the Normal Control responds above the assay cutoff within normal limits. Individual laboratories must establish their own values and limits of variance based upon the appropriate assay's performance.

## **5. Statement of Intended Use**

SPOTCHECK Blood Spot Controls are used for monitoring assay performance during *in vitro* diagnostic newborn screening for deficient Galactose-1-phosphate Uridyltransferase (GALT) and/or Biotinidase enzyme activity. Enzyme response quantitation is provided in the product insert.

The controls are treated in the same manner as patient samples in the course of analysis, and are intended for use by trained, qualified laboratory personnel.

## **6. Blood Spot Controls Activity Verification**

Each manufactured lot of blood spot controls is analyzed to verify that either the Normal Control contains sufficient enzyme activity to be labeled as normal or conversely, that the Deficient Control has clinically deficient enzyme activity. Control lots are individually tested using FDA-cleared SPOTCHECK Biotinidase and Uridyl Transferase 50-Hour Reagent Kits to determine the response of each analyte (enzyme) present. The controls are analyzed in Astoria-Pacific's laboratory on dedicated SPOTCHECK systems maintained for quality control purposes. Results are included in the product insert.

## **7. Stability**

Recommended storage conditions for the Blood Spot Controls are < -10 degrees Celsius and desiccated. Stored in this manner, the controls are stable for a minimum of 2 years from the manufacture date.



## DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration  
10903 New Hampshire Avenue  
Document Mail Center – WO66-0609  
Silver Spring, MD 20993-0002

Astoria-Pacific, Inc.  
c/o Mr. Charles A. Peterson, CEO  
15130 SE 82<sup>nd</sup> Dr.  
Clackamas, OR 97015

DEC 14 2009

Re: k090940

Trade/Device Name: Astoria-Pacific SPOTCHECK® Blood Spot Controls  
Regulation Number: 21 CFR 862.1660  
Regulation Name: Quality control material (assayed and unassayed)  
Regulatory Class: Class I, reserved  
Product Code: JJT  
Dated: October 19, 2009  
Received: October 21, 2009

Dear Mr. Peterson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'CCH', with a long horizontal flourish extending to the right.

Courtney C. Harper, Ph.D.  
Director  
Division of Chemistry and Toxicology  
Office of *In Vitro* Diagnostic Device  
Evaluation and Safety  
Center for Devices and Radiological Health

Enclosure

**Indication For Use**

510(k) K090940

Device Name: Astoria-Pacific SPOTCHECK® Blood Spot Controls

Indication For Use:

SPOTCHECK Blood Spot Controls are used for monitoring assay performance during *in vitro* diagnostic newborn screening for deficient Galactose-1-phosphate Uridyltransferase (GALT) and/or Biotinidase enzyme activity. Enzyme response quantitation is provided in the product insert.

Prescription Use   X    
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use       
(21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)



Division Sign-Off  
Office of In Vitro Diagnostic Device  
Evaluation and Safety

510(k) K090940