K062932

Ahlstrom

510(k) Summary

OCT 19 2007

Submitter: Ahlstrom Filtration LLC.
122 West Butler Street
Mount Holly Springs, PA 17065
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Contact: Heather Mowers **Preparation Date:** September 13, 2006

Product name - Trade: Ahlstrom 226 specimen collection paper
Common: Specimen collection paper

Classification name: tubes, vials, systems, serum separators, blood collection
Class: II **Product code:** JKA
Applicable CFR Section : 21 CFR 862.1675: Blood specimen collection device

Predicate device:
Whatman Body Fluid Collection Paper: Whatman BFC 18. K932661

Device description:
Ahlstrom 226 specimen collection paper is designed to provide a uniform surface for the collection of blood spots. A drop of blood is applied to the filter paper and allowed to soak through the paper. The sample is then air dried and sent to a laboratory for further analysis.

This specimen collection paper is made from 100 % pure cotton linters with no wet-strength additives added and conforms to the Recognized Consensus Standard NCCLS LA4-A3.

This device has 4 crucial performance characteristics that can be performed with lysed or intact red blood cells: blood absorption time, blood spot diameter, serum absorption volume, and homogeneity.

Intended use:
The Ahlstrom 226 specimen collection paper is intended to be used as a medium to collect and transport blood specimen spots to a laboratory. The 226 paper will be in the format of a printed card that may be incorporated along with a tear-apart form for demographic information.

Description of device design requirements:

Critical physical properties during manufacturing are basis weight, pH and ash.

1) Manufactured from 100% pure cotton fiber with no wet strength additives.
2) Basis weight should be 110 lb +/- 5% per ream (179 g/m^2 +/- 5%). A ream is defined as 500 sheets 24" x 36" (ASTM D646-96).
3) The pH should be 5.7 to 7.5 (Test method ISO 6599:1981).
4) Ash %: 0.1% maximum (Test method A of ASTM D586-97a).
5) Manufacturer's name and lot number are indicated on the filter paper portion of all specimen collection devices.
6) Printed devices contain at minimum the following information:
   - Infant's name (last [and first if available])
   - Mother's first and last name (optional: include mother's maiden name)
   - Sex
   - Birth date (optional: include time of birth)
   - Date of specimen collection
   - Infant's age (indicate if less than 24 hours; optional: include address and phone number)
   - Patient identification number (e.g., medical record number; optional: include address and phone number)
   - Birth weight
   - Submitter's identification and address (optional: include birth facility)
   - Physician's name (healthcare provider) and telephone number
   - Name of newborn screening program and address
   - Unique non-repeating serial number
   - Expiration date of specimen collection device
   - Appropriate number of preprinted circles
   - Manufacturer and lot number of the filter paper indicated on the filter paper section, and manufacturer or printer listed on the patient information section of the form.

Description of the test method used:

The test method used can be found in the Recognized Consensus Standard: NCCLS LA4-A3, Blood Collection on Filter Paper for Neonatal Screening Programs; Approved Standard – Third Edition (1997) from the National Committee for Clinical Laboratory Standards (NCCLS). The performance specifications in this document include:

Mean blood absorption time:	Lysed red blood cells = 5 – 30 seconds
	Intact red blood cells = 5 – 30 seconds
Mean blood-spot diameter:	Lysed red blood cells = no range published
	Intact red blood cells = 15 – 17mm
Mean serum-absorption volume:	Lysed red blood cells = 1.11 – 1.49 µL
	Intact red blood cells = 1.37 – 1.71µL

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Homogeneity:	Lysed red blood cells p >0.05 Intact red blood cells p >0.05

Samples of three lots of Ahlstrom 226 specimen collection paper were sent to the Centers for Disease Control and Prevention Newborn Screening Quality Assurance Program (CDC) for evaluation using the NCCLS LA4-A3 standard applied to a solution of intact and/or lysed red blood cells. The CDC's report indicated that the parameters tested were within acceptable limits.

Additionally, samples from each of the lots of material tested by the CDC were sent to an independent testing laboratory for serum absorption volume and blood spot diameter testing following the same NCCLS standard. The purpose of this testing was to compare the results for absorption volume and blood spot diameter to the CDC results and to compare lots of material run at different times to ensure consistency over time. The results of this testing were also within acceptable limits.

Labeling/Packaging:
Printed forms are to be packaged in a manner such that they will not become compressed. Chemicals or other types of specimens should not be packaged in the same container used for shipment of blood spot specimens.

Conclusions:
The information provided in the pre-market notification demonstrates that Ahlstrom 226 Specimen Collection Paper is substantially equivalent to the predicate device. This equivalence was demonstrated through comparison of intended uses, physical properties, and specifications found in the Recognized Consensus Standard NCCLS LA4-A. The information supplied in the pre-market notification provides reasonable assurance that Ahlstrom 226 Specimen Collection Paper is safe and effective for the stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Ahlstrom Filtration LLC
C/o Ms. Heather Mowers
Research Associate
122 West Butler Street
Mount Holly Springs, PA 17065

FEB 06 2015

Re: K062932
Trade/Device Name: Ahlstrom 226 Specimen Collection Paper
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood specimen collection device
Regulatory Class: Class II
Product Code: PJC
Dated: July 12, 2007
Received: July 23, 2007

Dear Ms. Mowers:

This letter corrects our substantially equivalent letter of October 19, 2007.

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809, please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for: Courtney H. Lias, Ph.D.
DIRECTOR
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062932

Device Name: Ahlstrom 226 Specimen Collection Paper

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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