



Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Ms. Paula Bulger  
Director, Regulatory Affairs  
AdvánDx, Inc.  
10A Rossler Road  
Woburn, MA 01901

MAR 26 2009

Re: k081433  
Trade/Device Name: EK/P *aeruginosa* PNA FISH  
Regulation Number: 21 CFR § 866.2660  
Regulation Name: Microorganism differential and identification device  
Regulatory Class: Class I  
Product Code: JSS  
Dated: January 23, 2009  
Received: January 27, 2009

Dear Ms. Bulger:

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 either class II (Special Controls) or class III (PMA), 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.

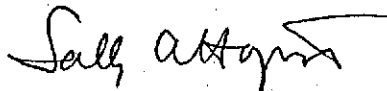
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

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This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at 240-276-0450. 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 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Sally A. Hojvat, M.Sc., Ph.D.  
Director  
Division of Microbiology Devices  
Office of *In Vitro* Diagnostic Device  
Evaluation and Safety  
Center for Devices and  
Radiological Health

Enclosure

**INDICATIONS FOR USE STATEMENT**

510(k) Number (if known):     K081433    

Device Name: EK/ *P. aeruginosa* PNA FISH

Indications for Use:

EK/*P. aeruginosa* PNA FISH is a multicolor, qualitative nucleic acid hybridization assay intended for identification of *Escherichia coli* /*Klebsiella pneumoniae* and *Pseudomonas aeruginosa* on smears from positive blood cultures containing Gram-negative rods. The test does not distinguish between *E. coli* and *K. pneumoniae*. Further testing is needed to differentiate *E. coli* and *K. pneumoniae*. The EK/*P. aeruginosa* PNA FISH assay is indicated for use in conjunction with positive blood subcultures as an aid in the identification of *E. coli*/*K. pneumoniae*, and/or *P. aeruginosa*.

Prescription Use     X      
(Part 21 CFR 801 Subpart D)

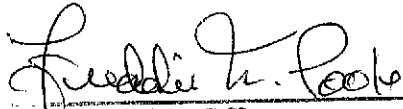
AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
Division Sign-Off

Office of In Vitro Diagnostic Device  
Evaluation and Safety

510(k)     K081433