



Advan Dx, Inc.
c/o Henrik Stender
Vice President Research and Development
400 Trade Center, Suite 6990
Woburn, MA 01801-7476

MAR 13 2012

Re: k092784

Trade/Device Name: *C. albicans/C. glabrata* PNA FISH™
Regulation Number: 21 § CFR 866.2660
Regulation Name: Microorganism differentiation and identification device
Regulatory Class: Class I
Product Code: NZS
Dated: January 28, 2010
Received: March 2, 2010

Dear Mr. Stender:

This letter corrects our substantially equivalent letter of March 12, 2010.

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 (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 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 Part 801); 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 Part 801), please go to

<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,



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

2A. INDICATIONS FOR USE STATEMENT

510(k) Number (if known):

Device Name: *C. albicans/C. glabrata* PNA FISH®

Indications for Use:

C. albicans/C. glabrata PNA FISH is a fluorescence qualitative nucleic acid hybridization assay intended for identification of *C. albicans* and/or *C. glabrata* on smears made from yeast positive blood cultures.

Subculturing of positive blood cultures is necessary to recover organisms for susceptibility testing and/or differentiation of mixed growth.

C. albicans/C. glabrata PNA FISH is indicated for use as an aid in the diagnosis of *C. albicans* and/or *C. glabrata* fungemia.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)


Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K092784