



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

AdvanDx, Inc.
c/o Benjamin S. Crystal
Clinical and Regulatory Affairs Manager
400 Trade Center, Suite 6990
Woburn, MA 01801

JAN 29 2013

Re: K121991

Trade/Device Name: *Enterococcus QuickFISH BC*
Regulation Number: 21 CFR 866.3740
Regulation Name: Streptococcus spp. serological reagents
Regulatory Class: Class I
Product Code: OAH
Dated: December 10, 2012
Received: December 11, 2012

Dear Mr. Crystal:

This letter corrects our substantially equivalent letter of January 7, 2013.

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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Uwe Scherf for

Sally A. Hojvat, M. Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure: Indications for Use Statement

510(k) Number (if known): K121991

Device Name: *Enterococcus QuickFISH BC*

Indications for Use:

Enterococcus QuickFISH BC is a multicolor, qualitative nucleic acid hybridization assay intended for the identification of *Enterococcus faecalis* and/or the detection of selected other enterococci on smears prepared from positive blood cultures containing gram-positive cocci in pairs and chains observed on Gram stain.

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

Enterococcus QuickFISH BC is indicated in an aid in the diagnosis of bacteremia caused by enterococci.

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)

Ragu Lt, Acting Branch Chief, Bac I

Division Sign-Off

Office of In Vitro Diagnostics and Radiological Health

510(k) K121991