DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

BIOMÉRIEUX
c/o Ms. Asa Karlsson
Regulatory Affairs Manager
5, rue des Aqueducs
69290 Craponne, France

NOV 17 2010

Re: K102668
Trade/Device Name: Etest®Tobramycin for Antimicrobial Susceptibility Test
Regulation Number: 21 CFR 866.1640
Regulation Name: Antimicrobial Susceptibility Test (AST) Powder
Regulatory Class: Class II
Product Code: JWY
Dated: September 17, 2010
Received: September 16, 2010

Dear Ms. Karlsson:

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).

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 Parts 801 and 809), 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 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/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

K102668

NOV 17 2010

Indications For Use

510(k) Number: K102668

Device Name: Etest® Tobramycin - Antimicrobial Susceptibility Test - MIC at 0.016-256 µg/mL and 0.064-1024 µg/mL.

Indications For Use: This submission is for Etest® Tobramycin for MIC determinations across 0.016-256 µg/mL and 0.064-1024 µg/mL with *Staphylococcus aureus*, *Enterobacteriaceae* and *P. aeruginosa.*

Etest® is a quantitative technique for determination of antimicrobial susceptibility of both non-fastidious Gram negative and Gram positive aerobic bacteria such as *Enterobacteriaceae, Pseudomonas, Staphylococcus* and *Enterococcus* species and fastidious bacteria, such as anaerobes, *N. gonorrhoeae, S. pneumoniae, Streptococcus* and *Haemophilus* species. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC) in µg/mL of different antimicrobial agents against microorganisms as tested on agar using overnight incubation.

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)

Freddie McCool

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K102668