AUG 20 1997

K972567

SUMMARY OF SAFETY AND EFFECTIVENESS

The Pasco MIC panels make use of established technology to quantitatively measure the susceptibility of rapidly growing aerobic and facultative anaerobic bacterial pathogens. The safety and efficacy of this product was determined by conducting QC performance testing at two laboratories through 25 consecutive days of testing. Endpoint results from the Pasco panels were compared to those from the reference panels and results from both panels were compared to published NCCLS recommended QC ranges.

Test results of the five recommended NCCLS strains (S. aureus ATCC 29213, E. faecalis ATCC 29212, P. aeruginosa ATCC 27853 and E. coli ATCC 25922) confirmed 100% Essential Agreement in which the Pasco endpoints either agreed exactly with or were within plus or minus one dilution of the reference panels. Additionally, MIC results from both the reference and the Pasco test panels were within the NCCLS recommended QC ranges published for Sparfloxacin.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Linda K. Dillon
Technical Manager
Pasco Laboratories, Inc.
12750 West Forty-Second
Wheat Ridge, Colorado 80033

AUG 20 1997

Re: K972567
Trade Name: Pasco MIC and MIC/ID Panels
Regulatory Class: II
Product Code: JWY
Dated: June 27, 1997
Received: July 1, 1997

Dear Ms. Dillon:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html"

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Device Name: **PASCO MIC and MIC/ID Panels; Inclusion of SPARFLOXACIN**

Indication For Use:

Pasco MIC and MIC/ID panels are used for quantitatively measuring (with the exception of the Breakpoint/ID panel which provides qualitative measurement of category results) the susceptibility of rapidly growing aerobic and facultative anaerobic bacterial pathogens to a battery of antimicrobial agents and determining the biochemical identification of those organisms.
This 510(k) notification is for the addition of Sparfloxacin to Pasco panels at concentrations of 0.03 to 8 mcg/ml for determining the susceptibility of bacterial pathogens with the exception of Haemophilus and S. Pneumoniae.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K972567