K001516

JUL 1 2 2000

(3)

# 510(k) SUMMARY

*(page 1 of 2)*

| | |
|---|---|
| DATE: | May 5, 2000 |
| CONTACT PERSON: | Linda K. Dillon<br>Chuck Lakel |
| TRADE NAME OF DEVICE: | Pasco MIC and MIC/ID Panels |
| COMMON NAME: | Antimicrobial Susceptibility Test |
| CLASSIFICATION NAME: | Class II Antimicrobial Susceptibility Test Microbiology Panel #83 |

SUBSTANTIAL EQUIVALENCE:
In review of previous 510(k) notifications for the Pasco MIC and MIC/ID panels (most recently: K992853, November 4, 1999 RE: Cefdinir; K992726, November 3, 1999 RE: Synercid (non-fastidious); K992717, November 2, 1999 RE: Synercid; K992646, October 19, 1999 RE: Penicillin; K992647, October 19, 1999 RE: Erythromycin; K992593, October 14, 1999 RE: Chloramphenicol; K992562, October 13, 1999 RE: Ceftriaxone; K992568, October 14, 1999 RE: Cefotaxime; K992507, October 18, 1999 RE: Trovafloxacin; K992546, October 12, 1999 RE: Meropenem; K992420, September 27, 1999 RE: Sparfloxacin; K992296, September 21, 1999 RE: Vancomycin; K992297, September 3, 1999 RE: Levofloxacin; K992143, September 16, 1999 RE: Clindamycin; K992108, September 3, 1999 RE: Cefepime; K992076, August 30, 1999 RE: Cefuroxime; K992059, August 30, 1999 RE: Imipenem; K992077, September 3, 1999 RE: Ofloxacin; K991925, August 20, 1999 RE: Amoxicillin/Clavulanic Acid; and K946126, January 17, 1995 RE: Detection of resistant pneumococci), the FDA has determined the Pasco panels to be substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments.

The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence as found in the Federal Food, Drug, and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E under which a device can be marketed without pre-market approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of, substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

DESCRIPTION OF THE DEVICE:
Varying concentrations of antimicrobial agents (usually in two-fold dilutions) are dispensed into the Pasco panels and the panels are then frozen. Panels are thawed prior to use, inoculated with the test organisms, incubated the traditional 16-24 hours and panels are then observed for visible growth or color changes as described in the package insert.

**510(k) SUMMARY**
*(page 2 of 2)*

The lowest concentration of each antimicrobial agent with no apparent visible growth of the test organism is recorded as the minimum inhibitory concentration (MIC). Changes in pH and production of specific metabolites from growth in biochemical substrates are interpreted as described in the package insert for conventional tubed media.

INTENDED USE FOR THE PASCO MIC AND MIC/ID PANELS:
PASCO MIC AND MIC/ID PANELS are used for quantitatively measuring (with the exception of the Breakpoint/ID panel which provides qualitative measurement or 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.

SUMMARY/CONCLUSION OF SUBSTANTIAL EQUIVALENCE TESTING:
Test panels containing Moxifloxacin at concentrations ranging from 8 – 0.015 mcg/ml were prepared in-house at Pasco using routine manufacturing procedures. Comparative testing of the Pasco test panel to a reference panel was performed at two sites using CDC challenge strains and clinical isolates.

Test results of the 101 *S. pneumoniae* strains demonstrated acceptable Essential Agreement (EA) of 98.7%. No major (M), very major (VM) or minor errors were observed. Category agreement (CA) was 100% . Test results of the 130 non-pneumococcal streptococci strains demonstrated acceptable Essential Agreement (EA) of 100%. No major (M), very major (VM) or minor errors were observed. Category Agreement (CA) was 100%.

QC endpoints for the QC organism *S. pneumoniae* ATCC 49619 from both the reference and Pasco panels throughout testing were within the recommended NCCLS acceptable range.

Reproducibility testing of 12 organisms at each site provided 11 organisms with on-scale endpoints. Overall reproducibility data demonstrated 100% within the acceptable plus or minus 1 dilution.

The results of the clinical testing, reproducibility testing and QC performance testing supports Substantial Equivalence as outlined in the FDA draft document "Review Criteria For Assessment Of Antimicrobial Susceptibility Devices" (May 1991).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 12 2000

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

Re: K001516
Trade Name: PASCO MIC and MIC/ID Panels (Moxifloxacin)
Regulatory Class: II
Product Code: JWY
Dated: May 5, 2000
Received: May 16, 2000

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 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). 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.

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" (21CFR 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 (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/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 Moxifloxacin**

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 Moxifloxacin to Pasco panels at concentrations of 8 – 0.015 mcg/ml for use in determining the susceptibility of *S. pneumoniae.*

Woody Dubois

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K001516

PRESCRIPTION USE X