DEC 16 1999

K993033

510(k) Summary

BioMed Diagnostics Incorporated has sought premarket approval for its proprietary InTray™ GC packaging of MTM media for isolation of pathogenic *Neisseria*, (83JTY).

Classification Name:

Culture Medium, for isolation of pathogenic *Neisseria*, (83JTY).

Common/Usual Name: Gonorrhoea isolation medium.

Trade/Proprietary Name: InTray™ GC

The InTray GC contains a Modified Thayer-Martin (MTM) medium within a sealed inner well. It has a two inch diameter well and 5-6ml of media. The inner seal that covers this well also covers another sealed cavity containing a CO_2 generating tablet. There is also an outer adhesive label seal with a window that does not fog up under 100% relative humidity. The user opens and reseals this outer label. In practice, when the user opens the outer seal, he may then remove and discard the inner seal exposing the surface of the medium and the sealed cavity. The next step is to inoculate the surface of the medium with the patient sample. Next, puncture the seal over the cavity with any convenient sharp point. Finally, reseal the outer label over the InTray. High humidity within the InTray causes the tablet to generate CO_2. Incubate the InTray and observe the growth of organisms through the window without opening the InTray and therefore without disturbing the atmosphere. Observation can be by eye, hand lens or microscope. This packaging has been used since 1994 for other BioMed media products.

Two one year studies were performed comparing the performance of room temperature stored InTray GC against fresh commercial MTM and chocolate media. Tests were performed in the laboratory using pure cultures at 10^2 cfu for each of four strains of *N. gonorrhoeae* and at 10^5 cfu for competing organisms. The four strains of *N. gonorrhoeae* included the NCCLS standard strain and three others drawn from a world wide data base. One of them was an AHU auxotype known to be difficult to grow. For two of the strains, recovered colony counts were comparable to fresh commercially prepared media. For the other two, colony counts were about half compared to fresh commercial media. In no case was there failure to recover the organism.

1430 Koll Circle, Suite 101, San Jose, CA 95112 • Tel (408) 451-0400 • Fax (408) 451-0409

The potential contaminants that were tested include *N. sicca, E. coli, S. epidermidis, P. mirabilis and C. albicans*. After one year at room temperature, the InTray GC was superior to fresh commercial media in suppressing growth of these organisms.

A clinical study was performed with 228 female patients using cervical swabs. Results positive for *N. gonorrhoeae* were identical to those for commercially prepared media, 18 positive, 210 negative. The principal contaminant was *C. albicans* with 17 positive for the InTray GC and 30 positive with the comparison MTM medium. There were no adverse indications in these tests.

In conclusion, the laboratory tests established the presumption of effectiveness and safety which was borne out by the clinical testing. The evidence indicates that InTray GC is superior for shelf life, ease of observation and suppression of *C. albicans*.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 16 1999

Mr. Robert D. Hall
President
BioMed Diagnostics, Inc.
1430 Koll Circle, Suite 101
San Jose, California 95112

Re: K993033
Trade Name: InTray™ GC
Regulatory Class: II
Product Code: JTY
Dated: September 3, 1999
Received: November 23, 1999

Dear Mr. Hall:

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.

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

510(k) Number (if known): K993033

Device Name: InTray™ GC

Indications For Use:

InTray GC is used, like conventional Thayer-Martin media plates, to grow *Neisseria gonorrhoeae* and similar organisms.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Woody Dubois

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K993033

Prescription Use X OR Over-The-Counter Use___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)