October 20, 2021

Biomed Diagnostics Incorporated
John Antiabong
Research and Development Director
1388 Antelope Road
White City, Oregon 97503

Re: K210511
Trade/Device Name: InTray GC
Regulation Number: 21 CFR 866.2410
Regulation Name: Culture Media for Pathogenic Neisseria Spp.
Regulatory Class: Class II
Product Code: JTY
Dated: February 23, 2021
Received: February 23, 2021

Dear John Antiabong:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR

803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ribhi Shawar, Ph.D. (ABMM)
Chief
General Bacteriology and Antimicrobial Susceptibility Branch
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

Device Name

Indications for Use *(Describe)*

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

February 12, 2021

510(k) Owner: Biomed Diagnostics, Inc. (Registration number 2951280)

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Contact person: Dr. John F Antiabong

Director Research and Development

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Device

Trade name: InTray® GC

Common name: Culture Medium For Pathogenic *Neisseria* Spp

Classification name: Culture medium for pathogenic *Neisseria* spp Class II, 21 CFR 866.2410, (Device product code: JTY).

Predicate device

InTray GC, 510K# K993033 cleared in 1999

Device description

The InTray GC is a Modified Thayer-Martin medium within a sealed inner well. The inner seal covers the inner well containing agar and an additional 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 inoculates the surface of the medium with the patient sample followed by resealing the outer adhesive label. High humidity within the InTray causes the tablet to generate CO_2 thus providing adequate bacterial growth condition for the target pathogen. After incubation of the inoculated InTray, the bacterial growth can be observed through the window without opening the InTray and therefore not disturbing the established CO_2 concentration. Observation of culture growth can be by eye, hand lens or microscope.

Intended Use

The InTray GC is a microbiological device intended to differentiate and support the growth of pathogenic *Neisseria gonorrhoeae* when incubated at 35°C for 24-72 hours. Inoculated samples can optionally be pre-incubated prior to transport when pre-incubated at 35°C for 24 hours. Subsequent transport, of the pre-incubated specimen under controlled room temperature (18 to 25°C), is supported out to 72 hours.

Substantial equivalence

The InTray GC (K210511) is substantially equivalent to the current legally marketed InTray GC (K993033). The InTray GC support the growth of pathogenic *Neisseria gonorrhoeae*. Both devices utilize the same technology by supporting *N. gonorrhoeae* on Modified Thayer-Martin medium. A transport simulation study as well as a comparative assessment study, using the InTray GC device, were conducted to determine the performance characteristics of InTray GC and to validate the new transportation claim. The study results showed that the InTray GC is acceptable for its intended use and is substantially equivalent to the predicate device. The table below shows the similarities and differences between the InTray GC and the predicate device.

Comparison of InTray GC with predicate device

SIMILARITIES		
Descriptive Category	**Subject Device: InTray GC Transport Function**	**Predicate Device: InTray GC (K993033)**
Indications for use	The InTray GC is a microbiological device intended to differentiate and support the growth of pathogenic *Neisseria gonorrhoeae* when incubated at 35°C for 24-72 hours. Inoculated samples can optionally be pre-incubated prior to transport when pre-incubated at 35°C for 24 hours. Subsequent transport, of the pre-incubated specimen under controlled room temperature (18 to 25°C), is supported out to 72 hours.	InTray GC is used, like conventional Thayer-Martin media plates, to grow *Neisseria gonorrhoeae* and similar organisms.
Device Product Code	JTY	Same
Prescription/over-the-counter use	Rx Only	Same
Collection apparatus	Does not include a specimen collection swab	Same
Reagents	Modified Thayer Martin medium (agar)	Same
Specimen type	Only sample intended for growth of *Neisseria* species	Same
Shelf-life	12 months	Same
DIFFERENCES		
Descriptive Category	**Subject Device: InTray GC Transport Function**	**Predicate Device: InTray GC (K933033)**
Transport claim	Transport at 18-25ºC for up to 72 hours	No transport

Non-clinical performance data

To demonstrate substantial equivalence of the InTray GC (K210511) to the previously cleared InTray GC (K993033) as a predicate device, Biomed Diagnostics Inc. performed data analysis on the recoverability of the *N. gonorrhoea*e after sample inoculation, transport simulation and incubation of both devices according to manufacturer's specifications. First, to determine the optimal specimen transport condition that ensures recovery of viable *N. gonorrhoeae* in the InTray GC, various transport conditions that simulated potential conditions in the healthcare operations were evaluated to determine the clinical utility of the InTray GC as a specimen transport device from site of collection to the laboratory. Four InTray replicates were inoculated with approximately 20 colony forming units (CFU) for each experimental group outlined in the table below and the process was repeated with the five different AR isolate bank strains (*N. gonorrhoeae* strains 0165, 0202, 0175, 0181 & 0197) and *N. gonorrhoeae* strain ATCC 43069. One lot of InTray GC transport device was used in the study.

Experimental groups

Experimental Group	Experimental Treatment Post Inoculation with 20 CFU *N. gonorrhoeae*		
	Pre-incubate:	Store:	Incubate*:
Group A	At 35°C for 24 hours	At 18-25°C for 72 hours	At 35°C for at least 72 hours
Group B	At 35°C for 24 hours	None	At 35°C for at least 72 hours
Group C1	No pre-incubation	At 18-25°C for 24 hours	At 35°C for at least 72 hours
Group C2	No pre-incubation	At 18-25°C for 48 hours	At 35°C for at least 72 hours
Group C3	No pre-incubation	At 18-25°C for 72 hours	At 35°C for at least 72 hours

*Also, continuous observation for up to 144 hours.

The data from the transport simulation study showed that inoculated samples pre-incubated at 35ºC for 24 hours followed by transport at 18-25ºC for 72 hours, demonstrated recovery via increased colony size when compared to samples that were not pre-incubated.

InTray GC transport and recovery was also compared to recovery using a legally marketed transport device and six *N. gonorrhoeae* strains. Multiple lots of variously aged InTray GC devices were used to test the six strains of *N. gonorrhoeae*, with 3 lots testing 5 strains (N=15 replicates) and two different lots testing one of the six strains (N=2 replicates). InTray GC devices were inoculated with 20 µL of a $1.5x10^3$ CFU/mL in 0.85% saline of each *N. gonorrhoeae* strain. Group B experimental design was used to establish time zero of incubation and Group A experimental design was used to evaluate the 72-hour transport claim - schematic in the Table above.

Three replicates of the legally marketed transport device were used to inoculate the same six *N. gonorrhoeae* strains, as those used for the InTray GC device, at an inoculum of $1.5x10^7$ CFU/mL in 0.85% saline. The legally marketed transport device was incubated at room temperature for 24-hours. Chocolate agar culture media was used for the determination of the organism recovery and for enumeration of the colony forming units recovered. The differences in inoculum concentration between InTray and the legally marketed transport device are to account for the 24-hour pre-incubation step and size of InTray GC device.

A decline in the CFU/mL of ≤ 2 $\log_{10}$ between time zero and the end of the experimental incubation was considered acceptable. The results of the comparative assessment study showed that there was ≤ 2 $\log_{10}$ CFU/mL difference in *N. gonorrhoeae* recovery, for each strain, between time zero (no transport) and the experimental endpoint (72-hour transport) for the InTray GC device. There was no difference between the performance of the predicate device and transported InTray GC device. Acceptable recovery performance was also achieved for the legally marketed transport device when time zero and the experimental endpoint of 24 hours were compared, demonstrating that sufficient viability of *N. gonorrhoeae* was achieved using traditional transport and culture techniques. The results also substantiate that the InTray GC device may be used for transport when following the new procedure.

Cross reactivity testing of the InTray GC device is already captured in the original 510K (K993033) and also presented in the instruction for use (IFU) document.

Conclusion

These performance characteristics therefore show that the InTray GC (K210511) is substantially equivalent to the previously cleared InTray GC (K993033) as an IVD for the transport of inoculated sample/specimen and subsequent recovery of *N. gonorrhoeae* in the laboratory.