FDA 510(k) Premarket Notification

# K210511 InTray GC

**CLEARED**

Oct 20, 2021
239 days to decision

K210511 · Product code: **JTY** · Microbiology
Source: https://www.510kdatabase.net/k210511/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Culture Media, For Isolation Of Pathogenic Neisseria (JTY) |
| Date received | Feb 23, 2021 |
| Decision date | Oct 20, 2021 |
| Days to decision | 239 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Biomed Diagnostics Incorporated** |
| Location | White City, OR, US |
| Contact | John F Antiabong |
| 510(k) history | 1 submissions · 1 cleared · 2021-2021 |