

K220739 Disposable Urine Collection TubeNov 17, 2022
248 days to decisionK220739 · Product code: **JSM** · Microbiology
Source: <https://www.510kdatabase.net/k220739/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Culture Media, Non-propagating Transport (JSM) |
| Date received | Mar 14, 2022 |
| Decision date | Nov 17, 2022 |
| Days to decision | 248 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Zhejiang Gongdong Medical Technology Co., Ltd. |
| Location | Taizhou, CN |
| Contact | Handson Wei |
| 510(k) history | 3 submissions · 3 cleared · 2020-2025 |

REGULATORY CONSULTANT

| | |
|-----------------|--|
| Consulting firm | Shanghai Mind-Link Consulting Co., Ltd. |
| Contact | Evan Hu |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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