

K232565 UriSponge™Oct 11, 2024
414 days to decisionK232565 · Product code: **JSM** · Microbiology
Source: <https://www.510kdatabase.net/k232565/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Culture Media, Non-propagating Transport (JSM) |
| Date received | Aug 24, 2023 |
| Decision date | Oct 11, 2024 |
| Days to decision | 414 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Copan Italia Spa |
| Location | Marlborough, MA, US |
| Contact | Silvia Caprini |
| 510(k) history | 8 submissions · 8 cleared · 1997-2024 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k232565/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026