

K231169 STERLINK plus Sterilizer with STERLOAD Cassette, Tyvek Roll with CI for STERLINK Sterilizer, Terragene Bionova SCBI (BT96), Terragene Bionova Reader Incubators (IC10/20FRLCD, Mini-bio), Terragene Chemdye (CD42), Terragene Cintape (CT40)May 25, 2023
30 days to decisionK231169 · Product code: MLR · General Hospital
Source: <https://www.510kdatabase.net/k231169/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Sterilizer, Chemical (MLR) |
| Date received | Apr 25, 2023 |
| Decision date | May 25, 2023 |
| Days to decision | 30 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Plasmapp Co.,, Ltd. |
| Location | Daejeon, KR |
| Contact | Seung Hun Lee |
| 510(k) history | 8 submissions · 8 cleared · 2021-2023 |

REGULATORY CONSULTANT

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|-----------------|--|
| Consulting firm | CardioMed Device Consultants, LLC |
| Contact | Candace Cederman |

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231169/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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