FDA 510(k) Premarket Notification

**CLEARED**

# K223023 Terragene Bionava SCBI (BT96), Terragene Bionova Reader Incubators (IC10/20FRLCD, Mini-bio), Terragene Chemdye (CD42), Terragene Cintape (CT40)

May 9, 2023
222 days to decision

K223023 · Product code: **FRC** · General Hospital
Source: https://www.510kdatabase.net/k223023/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Indicator, Biological Sterilization Process (FRC) |
| Date received | Sep 29, 2022 |
| Decision date | May 9, 2023 |
| Days to decision | 222 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Plasmapp Co,., Ltd.** |
| Location | Daejeon, KR |
| Contact | Byeong Geon Song |
| 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