FDA 510(k) Premarket Notification

CLEARED

K212193 Terragene Bionova SCBI (BT96), Terragene Bionova Reader Incubators (IC10/20FRLCD, Mini-bio), Terragene Chemdye (CD42), Terragene Cintape (CT40)

Oct 22, 2021
100 days to decision

K212193 · Product code: **FRC** · General Hospital
Source: https://www.510kdatabase.net/k212193/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Indicator, Biological Sterilization Process (FRC)
Date received	Jul 14, 2021
Decision date	Oct 22, 2021
Days to decision	100 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

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