

K220345 STERLINK mini Sterilizer with STERLOAD mini Cassette, Tyvek Roll with CI for STERLINK Sterilizer, Sterilization Process Indicator for STERLINK SterilizerApr 14, 2023
431 days to decisionK220345 · Product code: **MLR** · General Hospital
Source: <https://www.510kdatabase.net/k220345/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sterilizer, Chemical (MLR)
Date received	Feb 7, 2022
Decision date	Apr 14, 2023
Days to decision	431 days
Third-party review	No
Summary / Statement	Summary
Other names	Terragene Bionova SCBI (BT96), Terragene Bionova Reader Incubators (IC10/20FRLCD, Mini-Bio), Terragene Chemdye (CD42), Terragene Cintape (CT40)

APPLICANT

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

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