

**K191021 Terragene Bionova, Terragene Bionova, Terragene
Integron, Terragene Cintape, Terragene Chemdye**Sep 13, 2019
149 days to decisionK191021 · Product code: **FRC** · General Hospital
Source: <https://www.510kdatabase.net/k191021/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Indicator, Biological Sterilization Process (FRC)
Date received	Apr 17, 2019
Decision date	Sep 13, 2019
Days to decision	149 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Terragene S.A.
Location	Rosario, AR
Contact	Maria Victoria Rocha
510(k) history	8 submissions · 7 cleared · 2017-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191021/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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