

K251122 Terragene® Bionova® BT20 Biological IndicatorAug 4, 2025
115 days to decisionK251122 · Product code: **FRC** · General Hospital
Source: <https://www.510kdatabase.net/k251122/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Indicator, Biological Sterilization Process (FRC)
Date received	Apr 11, 2025
Decision date	Aug 4, 2025
Days to decision	115 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Terragene
Location	Alvear, AR
Contact	Hernando Carrizo
510(k) history	1 submissions · 1 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251122/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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