

K221641 Terragene® Bionova® Hyper Biological Indicator (BT98), Terragene® Bionova® Hyper Auto-reader Incubator (BHY), Terragene® Bionova® NanoBio Auto-reader Incubator (BNB)Feb 28, 2023
267 days to decisionK221641 · Product code: **FRC** · General Hospital
Source: <https://www.510kdatabase.net/k221641/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Indicator, Biological Sterilization Process (FRC)
Date received	Jun 6, 2022
Decision date	Feb 28, 2023
Days to decision	267 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k221641/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026