

**K231383 Terragene® Bionova® Self-Contained Biological Indicator (BT95), Terragene® Bionova® Self-Contained Biological Indicator (BT96), Terragene® Chemdye® Chemical Process Indicator (CD42), Terragene® Cintape® Chemical Process Indicator Tape (CT40)**Sep 18, 2024  
495 days to decisionK231383 · Product code: FRC · General Hospital  
Source: <https://www.510kdatabase.net/k231383/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Indicator, Biological Sterilization Process (FRC)
Date received	May 12, 2023
Decision date	Sep 18, 2024
Days to decision	495 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Licensale, Inc.</b>
Contact	Raymond Kelly

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k231383/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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