

**K163646 Terragene Bionova(R) SCBI (BT220, BT221, BT222, BT223), Terragene Bionova (R) PCD (PCD220-C, PCD220-2, PCD222-C, PCD222-2), and Terragene Bionova(R) IC10/20FR Reader Incubator**Nov 2, 2017  
314 days to decisionK163646 · Product code: FRC · General Hospital  
Source: <https://www.510kdatabase.net/k163646/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Indicator, Biological Sterilization Process (FRC)
Date received	Dec 23, 2016
Decision date	Nov 2, 2017
Days to decision	314 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k163646/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026