

**K133322 STERITEC SMART-READ BIOLOGICAL TEST PACK  
WITH INSTANT READOUT INTEGRATOR**

Aug 25, 2014  
300 days to decision

K133322 · Product code: **FRC** · General Hospital  
Source: <https://www.510kdatabase.net/k133322/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Indicator, Biological Sterilization Process (FRC)
Date received	Oct 29, 2013
Decision date	Aug 25, 2014
Days to decision	300 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Steritec Products Mfg Co, Inc.</b>
Location	Castle Rock, CO, US
Contact	JONATHAN RUTIGLIANO
510(k) history	22 submissions · 22 cleared · 1996-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k133322/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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