

**K141312 STERILUCENT PROCESS CHALLENGE DEVICE**Oct 31, 2014  
164 days to decisionK141312 · Product code: **FRC** · General Hospital  
Source: <https://www.510kdatabase.net/k141312/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Indicator, Biological Sterilization Process (FRC)
Date received	May 20, 2014
Decision date	Oct 31, 2014
Days to decision	164 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sterilucent, Inc.</b>
Location	Minneapolis, MN, US
Contact	PETER KALKBRENNER
510(k) history	7 submissions · 7 cleared · 2014-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k141312/> 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 June 28, 2026