

**K183294 CELERITY 20 HP Biological Indicator, CELERITY HP Challenge Pack**

Jan 3, 2019  
37 days to decision

K183294 · Product code: **FRC** · General Hospital  
Source: <https://www.510kdatabase.net/k183294/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Indicator, Biological Sterilization Process (FRC)
Date received	Nov 27, 2018
Decision date	Jan 3, 2019
Days to decision	37 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>STERIS Corporation</b>
Location	Mentor, OH, US
Contact	Anthony Piotrkowski
510(k) history	204 submissions · 202 cleared · 1997-2026

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

Device record: <https://www.510kdatabase.net/k183294/>. Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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