

**K192001 Steriluent self-Contained Biological Indicator,
Steriluent Lumen Cycle Process Challenge Device, Steriluent
Flexible Cycle Process Challenge Device**Oct 22, 2019
88 days to decisionK192001 · Product code: **FRC** · General Hospital
Source: <https://www.510kdatabase.net/k192001/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Indicator, Biological Sterilization Process (FRC)
Date received	Jul 26, 2019
Decision date	Oct 22, 2019
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Steriluent, Inc.
Location	Minneapolis, MN, US
Contact	Peter Kalkbrenner
510(k) history	7 submissions · 7 cleared · 2014-2019

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