

K251452 Celerity 5 HP Biological Indicator (LCB052)Jun 6, 2025
28 days to decisionK251452 · Product code: **FRC** · General Hospital
Source: <https://www.510kdatabase.net/k251452/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Indicator, Biological Sterilization Process (FRC)
Date received	May 9, 2025
Decision date	Jun 6, 2025
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Celerity 5 HP Challenge Pack (LCB059); Celerity 20 HP Biological Indicator (LCB044); Celerity 20 HP Challenge Pack (LCB045)

APPLICANT

Company	Steris
Location	Mentor, OH, US
Contact	Logan Persons
Website	https://www.steris.com
510(k) history	21 submissions · 19 cleared · 2021-2026

Steris is a leading global provider of products and services supporting patient care with emphasis on infection prevention. The company operates with a manufacturing facility in Mentor, Ohio, and serves hospitals, surgery centers, pharmaceutical manufacturers, and research laboratories worldwide. Steris has received FDA 510(k) clearances from total submissions since 2021. The company specializes in General Hospital devices, which represent 81% of its regulatory submissions. Recent clearances include sterilization systems, chemical indicators, biological indicators, and wa...