FDA 510(k) Premarket Notification

K231490 Celerity 20 HP Biological Indicator

CLEARED

Aug 7, 2023
76 days to decision

K231490 · Product code: **FRC** · General Hospital
Source: https://www.510kdatabase.net/k231490/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Indicator, Biological Sterilization Process (FRC)
Date received	May 23, 2023
Decision date	Aug 7, 2023
Days to decision	76 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	VERIFY V24 Self-Contained Biological Indicator

APPLICANT

Company	**STERIS Corporation**
Location	Mentor, OH, US
Contact	Gregory Land
510(k) history	204 submissions · 202 cleared · 1997-2026