

K234084 STERRAD™ Chemical Indicator (CI) Strip (14100)Jul 5, 2024
196 days to decisionK234084 · Product code: **JOJ** · General Hospital
Source: <https://www.510kdatabase.net/k234084/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Indicator, Physical/chemical Sterilization Process (JOJ)
Date received	Dec 22, 2023
Decision date	Jul 5, 2024
Days to decision	196 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	STERRAD® SEALSURE® Chemical Indicator (CI) Tape (14202NL); STERRAD VELOCITY™ Biological Indicator (BI) (43210) (60 count); STERRAD VELOCITY™ Biological Indicator (BI) (43210-30)(30 count); STERRAD VELOCITY™ Reader (43220); ULTRA GI™ Process Challenge Device (PCD) (43400)(30 count)

APPLICANT

Company	Advanced Sterilization Products, Inc.
Location	Irvin, CA, US
Contact	Brandon Roberts
510(k) history	5 submissions · 5 cleared · 2021-2026

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