

K261897 HALYARD* ARMOR-FLEX* Sterilization Wrap with ASSURE-DRY* Technology

Jul 2, 2026
27 days to decision

K261897 · Product code: FRG · General Hospital
Source: <https://www.510kdatabase.net/k261897/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wrap, Sterilization (FRG)
Date received	Jun 5, 2026
Decision date	Jul 2, 2026
Days to decision	27 days
Third-party review	Yes
Summary / Statement	Summary
Other names	HALYARD* HEAVY-FLEX* Sterilization Wrap with ASSURE-DRY* Technology; HALYARD* STANDARD-FLEX* Sterilization Wrap with ASSURE-DRY* Technology; HALYARD* H300W Sterilization Wrap with ASSURE-DRY* Technology

APPLICANT

Company	O&M Halyard, Inc.
Location	Alpharetta, GA, US
Contact	Anureet Singh
510(k) history	26 submissions · 26 cleared · 2019-2026