

K260725 BAÜMER Surgical Gowns (COP01, COP04, COP05, COP10)May 12, 2026
68 days to decisionK260725 · Product code: FYA · General Hospital
Source: <https://www.510kdatabase.net/k260725/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Mar 5, 2026
Decision date	May 12, 2026
Days to decision	68 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hindernis DE Mexico, S.A.P.I. DE C.V.
Location	Naucalpan De Juarez, MX
Contact	Eduardo Gras
510(k) history	1 submissions · 1 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	Manton Business and Technology Services
Contact	Charles Shen

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k260725/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 6, 2026