May 12, 2026

Hindernis DE Mexico, S.A.P.I. DE C.V.
% Charles Shen
Vice President
Manton Business and Technology Services
37 Winding Ridge
Oakland, New Jersey 07436

Re: K260725
Trade/Device Name: BAÜMER Surgical Gowns (COP01, COP04, COP05, COP10)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYA
Dated: March 5, 2026
Received: March 5, 2026

Dear Charles Shen:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

ALLAN GUAN -S

For Bifeng Qian, M.D., Ph.D.
Assistant Director
DHT4C: Division of Infection
Control Devices
OHT4: Office of Surgical and
Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260725

Device Name
BAÜMER Surgical Gowns (COP01, COP04, COP05, COP10)

Indications for Use *(Describe)*
BAÜMER Surgical Gowns (COP01, COP04, COP05, and COP10) are intended to be worn by healthcare professionals to help protect both the patients and the healthcare professionals from the transfer of microorganisms, body fluids, and particulate material.

They are classified as Level 4 surgical gowns in accordance with ANSI/AAMI PB70 and used in healthcare facilities. The gowns are single use, disposable, and provided sterile.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K260725

510(k) Summary:

This summary of 510(k) safety and effectiveness information is being submitted In accordance with the requirements of 21CFR 807.92

1.0 Submitter Information

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Date of Summary: April 09, 2026

2.0 Device Information

Proprietary Name:	BAÜMER Surgical Gowns (COP01, COP04, COP05, and COP10)
Device Common Name:	Gown, Surgical
Classification Name:	Gown, Surgical
Classification Regulation:	878.4040
Class:	Class 2
Panel:	General Hospital
Product Code:	FYA

3.0 Predicate Device Information:

The BAÜMER Surgical Gowns (COP01, COP04, COP05, and COP10) described in this premarket notification are substantially equivalent to the following device:

(1) K200522, "AERO CHROME Breathable Performance Surgical Gowns", manufactured by "O & M Halyard Inc" located in Mechanicsville, VA, USA.

4.0 Device description:

BAÜMER Surgical Gowns have four different models, which are: COP01, COP04, COP05, and COP10

- **COP01**: Surgical Gown
- **COP04:** Ultra Breathable Surgical Gown
- **COP05**: High Performance Surgical Gown
- **COP10**: Surgical Gown for Surgical Assistant

They are full length, constructed with raglan sleeves, hook and loop neck closures, and tie waist closures.

Model COP01 and Model COP10 are made from SMMS Repellent 43 Gram material at the chest and sleeve area (critical zone), while Model COP04 is made from BVB 60 Gram material at the chest and sleeve area (critical zone). Model COP05 is made from BVB 60 Gram material at the sleeve area, and SMMS Repellent 43 Gram material, enforced with PP/PE material at the chest area.

All models provide Level 4 protection per ANSI/AAMI PB70 standard.

BAÜMER Surgical Gown, Models COP01, COP04, COP05, and COP10 have four different sizes: Large (L), Extra Large (XL), and Extra Extra Large (XXL), and Super Extra large (XXXL).

All gowns are sterilized with Co 60 radiation.

5.0 Indications for Use:

The BAÜMER* SURGICAL GOWNS (COP01, COP04, COP05, and COP10) are intended to be worn by healthcare professionals to help protect both the patients and the healthcare professionals from the transfer of microorganisms, body fluids, and particulate material. They are classified as Level 4 surgical gowns in accordance with ANSI/AAMI PB70 and used in healthcare facilities. The gowns are single use, disposable, and provided sterile

6.0 Comparison to Predicate Devices

The BAÜMER Surgical Gowns (COP01, COP04, COP05, and COP10) described in this premarket notification are compared to the following device:

(1) K200522, "AERO CHROME Breathable Performance Surgical Gowns", manufactured by "O & M Halyard Inc" located in Mechanicsville, VA, USA.

The following table shows similarities and differences of use, design, and material between our device and the predicate devices.

Table 1: Comparison of Intended Use, Design, and Material

Description	Subject Device	Predicate Device (K200522)	Comparison Analysis
Product Code	FYA	FYA	Same
Regulation Number	21 CFR 878.4040	21 CFR 878.4040	Same
Classification	Class 2	Class 2	Same
Indication for Use	The BAÜMER* SURGICAL GOWNS (COP01, COP04, COP05, and COP10) are intended to be worn by healthcare professionals to help protect both the patients and the healthcare professionals from the transfer of microorganisms, body fluids, and particulate material. They are classified as Level 4 surgical gowns in accordance with ANSI/AAMI PB70 and used in healthcare facilities. The gowns are single use, disposable, and provided sterile	AERO CHROME* Breathable Performance Surgical Gowns are sterile, single use surgical apparel intended to be worn by healthcare professionals to help protect both the patient and the healthcare worker from the transfer of microorganisms, body fluids, and particulate matter. The AERO CHROME* Breathable Performance Surgical Gowns meet the Level 4 AAMI PB70 Liquid Barrier classifications.	Similar
Basic Design	Full length, constructed with raglan sleeves, neck closures, and waist closures.	Full length, constructed with raglan sleeves, neck closures, and waist closures.	Same
Features	Regular and Reinforced	Regular and Reinforced	Same
Materials	SMMS nonwoven, BVB, Polyester, PE/SPP	SMS nonwoven, Polyester and Polyamide	Similar
Protection Level	Level 4 per ANSI/AAMI PB70	Level 4 per ANSI/AAMI PB70	Same

Sizes	L, XL, XXL, XXXL	Small, Large, X-Large, XX-Large, XXX-Large, X-Long XL, X-Long XXL	Similar
Single Use	Yes	Yes	Same
Color	Blue	Blue	Same
Sterile	Sterile	Sterile	Same
Labeling	Conform with 21CFR Part 801	Conform with 21CFR Part 801	Same

The subject device and predicate device are similar in use, design, and material. The minor differences between the subject device and predicate device do not raise any concerns in terms of safety and effectiveness.

The following table shows similarities and differences of performances between our device and the predicate device.

Table 2: Comparison of Device Performance

Description	Subject Device	Predicate Device (K200522)	Comparison Analysis
ANSI/AAMI PB70	Level 4 Liquid Barrier for Critical Zone Level 4 Liquid Barrier for Non-Critical Zone Level 4 Liquid Barrier for Sleeve Seam Level 4 Liquid Barrier for Shoulder Seam Level 4 Liquid Barrier for tie attachment area	Level 4 Liquid Barrier for Critical Zone Level 1 Liquid Barrier for Non-Critical Zone	Better than Predicate device
Biocompatibility Per ISO 10993-1	Under the conditions of the study: non-cytotoxic, non-irritant, and non-sensitizing	Under the conditions of the study: non-cytotoxic, non-irritant, and non-sensitizing	Identical
Water Vapor Transmission Rate of Materials (MOCON)	Not performed	Pass	This is not a mandatory test
Linting per ISO 9073-10	Average ≤ 10000 (Log L < 4.0)	Pass	Similar
Tensile/ Breaking Strength and Elongation per ASTM D5034	Pass MD Mean ≥ 10 N; CD Mean ≥ 10 N	Pass	Identical

Tearing Strength per ASTM D5733-99	Pass: MD Mean ≥ 30 N; CD Mean ≥ 30 N	N/A	Not reported by predicate device
Seam Strength per ASTM D1683	≥ 30 N	N/A	Not reported by predicate device
Peel Strength per STM-00197	Not performed	Pass	This is not a mandatory test
Hydrohead Testing	Not performed	Pass	This is not a mandatory test
Abrasion Testing per STM-00149	Not performed	Pass	This is not a mandatory test
Flammability of Clothing Textiles per 16 CFR Chapter II	Class 1	Class 1	Identical
Air Permeability (Back of Gown) per STM-00162	Not performed	Pass	This is not a mandatory test
SAL	10^{-6}	10^{-6}	Identical
Sterilization Modality	Radiation	EtO	Similar

7.0 Non-Clinical Study Summary

Non clinical tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device complies with the following standards:

Table 3: Summary of Non-Clinical Studies

Test Standard	Purpose	Acceptance Criteria	Results
AATCC127	Water resistance/ Hydrostatic Pressure	≥ 50 cm for critical zone ≥ 50 cm for non-critical zone ≥ 50 cm for sleeve seam ≥ 50 cm for shoulder seam ≥ 50 cm for tie attachment area	Pass

ASTM F1671	Resistance to Penetration by Blood Born Pathogen	No Penetration for critical zone No Penetration for non-critical zone No Penetration for sleeve seam No Penetration for shoulder seam No Penetration for tie attachment area	Pass
ASTM D5034-09	Tensile Strength	MD Mean ≥ 30 N; CD Mean ≥ 30 N	Pass
ASTM D5733-99	Tearing Strength	MD Mean ≥ 10 N; CD Mean ≥ 10 N	Pass
ISO 9073-10	Linting	Average ≤ 10000 (Log L < 4.0)	Pass
ASTM D1683	Seam Strength	≥ 30 N	Pass
16 CFR 1610	Flammability testing	Meet CPSC 1610 Class 1	Pass
ASTM F88	Sterile barrier seal strength	> 60 N	Pass
ASTM F1929	Sterile barrier dye penetration	No penetration	Pass
ISO 10993-5	In vitro cytotoxicity	Under conditions of the study, not cytotoxic	Pass
ISO 10993-23	Irritation	Under the conditions of the study, not an irritant	Pass
ISO 10993-10	Skin sensitization	Under conditions of the study, not a sensitizer	Pass
ISO 11137/ ISO 13004	Sterilization Validation	SAL level of 10^{-6}	Pass

8.0 Clinical Study Summary

Clinical study was not performed for this product.

9.0 Conclusion

The conclusions drawn from the nonclinical tests that demonstrate is that the subject device is as safe, as effective, and performs as well as or better than the legally marketed device.