This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.

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Guidance on

Premarket Notification [510(k)] Submissions

for

Surgical Gowns and Surgical Drapes

Infection Control Devices Branch

Division of General and Restorative Devices

August, 1993

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Preface

This guidance was developed by the Infection Control Devices Branch, Division of General and Restorative Devices (DGRD), Office of Device Evaluation (ODE), Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA).

FDA regulates the introduction of medical devices into interstate commerce. A person intending to market surgical gowns or surgical drapes must submit to FDA, and have cleared, a premarket notification [510(k)] submission prior to its introduction into interstate commerce. Regulations governing the general content and format of 510(k) submissions are codified under 21 Code of Federal Regulations, Part 807. These and other regulatory requirements pertaining to the marketing of a new medical device are discussed in guidance documents available from the CDRH Division of Small Manufacturers Assistance (DSMA). The intent of this guidance document is to provide 510(k) applicants specific additional directions regarding information and data which should be submitted to FDA in a 510(k) submission for surgical gowns and surgical drapes.

A safe and effective barrier device to protect both the surgical patient and the operating room personnel from the transfer of microorganisms or body fluids during surgical procedures is important in preventing infections. Comprehensive, scientifically sound criteria for the evaluation of surgical gowns or surgical drapes is essential to help ensure that these devices are safe and effective for their intended use when used according to their labeling. FDA recognizes the importance of providing applicants, and other interested parties, the agency's 510(k) submission criteria for surgical gowns or surgical drapes in order to facilitate assembly of necessary data, to maintain consistency of review, and to provide for a more efficient regulatory process.

The document expresses FDA's recommendations as of the date noted on the cover page. There is ongoing research and debate with regard to the design and test methods for surgical gowns and surgical drapes. Despite this state of flux, FDA finds it necessary at this time to document its 510(k) submission criteria in order to expedite the availability of safe and effective surgical gowns and surgical drapes. FDA expects that this document will stimulate and/or accelerate development of test methods and specific validation procedures by the scientific community and regulated industry. The document is not static but will be periodically revised to keep it current with state of the art developments in this area. Comments on the document are welcome and should be sent to the address noted on page 11.

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I. Introduction

A. Scope

This document establishes the 510(k) review requirements for surgical gowns and surgical drapes.

Exclusions

Surgical suits and dresses, commonly known as scrub suits, which are exempted in the surgical apparel classification regulation, will not be included in this Guidance. Surgical masks, which are included in the classification regulation for surgical apparel, will be the subject of another guidance document.

B. Purpose

This guidance is intended to:

1. assist persons (manufacturers, distributors, or importers) in organizing premarket notifications for surgical gowns and surgical drapes;

2. achieve consistency in meeting the requirements and in the presentation of information; and

3. guide FDA review staff in conducting and documenting the review of premarket notifications.

C. Definitions

1. Surgical Gown: Described in 21 CFR §878.4040 as surgical apparel worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material.

2. Surgical Drape: Described in 21 CFR §878.4370 as a device made of natural or synthetic materials intended to be used as a protective patient covering, such as to isolate a site of surgical incision from microbial and other contamination.

3. Intended Use: A statement of all conditions, purposes, uses for which such device is intended, including conditions, purposes, or uses for which it is recommended, prescribed, or suggested in its oral, written, printed or graphic advertising or uses for which the device is commonly used. Conditions include: single use only, disposable, and reusable.

4. Sterility Assurance Level (SAL): A value indicating the probability of a survivor after a sterilization process. For example, an SAL of 10^{-6} is the probability of one in one million nonsterile units after exposure to a sterilization process.

5. Abbreviations:

AAMI - Association for the Advancement of Medical Instrumentation

AATCC - American Association of Textile Chemists and Colorfastness

CPSC - Consumer Products Safety Commission

ASTM - American Society for Testing and Materials

CFR - Code of Federal Regulations

NFPA - National Fire Protection Association

SMDA - Safe Medical Devices Act of 1990

DSMA - Division of Small Manufacturers Assistance

ODE - Office of Device Evaluation

OC - Office of Compliance

D. Principles Regarding Presentation of Data

1. Editorial Considerations: The 510(k) should be carefully edited as well as scientifically reviewed before it is submitted to FDA. It should be proofread to assure that all pages are properly indicated, consecutive, distinctly copied, and readable.

2. Abbreviations: Standard abbreviations acceptable to a significant peer reviewed journal should be used wherever possible. All other abbreviations should be identified at the beginning of each section in which they are used or in footnotes to tables and graphs.

3. Data Availability: The document outlines typical circumstances of data review. It is not possible to anticipate all situations that may require further FDA analyses. Thus, submitters should be aware that they may be asked, at FDA's discretion, to submit additional data or to present data in another format or to provide more detailed explanations of the information submitted.

   Applicants should keep data used for the 510(k) submission in a controlled and well organized format. This will allow the firm to expeditiously supply FDA with additional information or analysis if required. Errors in data that are identified by the applicant after submission to FDA should be brought to FDA's attention immediately.

4. Tables and Graphs: Well-constructed tables are fundamental to the reporting and evaluation of data. All tables should be clearly identified and captioned with symbols keyed to a footnote or accessible reference page that adequately indicates the nature of

the data.

Graphs should supplement, not replace, data tables. They should be of a quality acceptable to a significant peer reviewed scientific journal.

5. Published Literature: Published methods or data referenced in study reports should be appended to the study report. Reprints of other referenced published reports or data should be appended to the section in which they are referenced. All referenced reports and data should be summarized including an explanation how it relates to the current submission.

E. Document Availability

The following relevant FDA documents are available from DSMA at (800)638-2041 or (301) 443-6597:

- Tripartite Biocompatibility Guidance for Medical Devices
- ODE Blue Book Memorandum #K90-1: 510 (k) Sterility Review Guidance
- Guidance on the Content of Premarket Notifications

II. Content and Organization of Information in a 510(k)

A. Cover Letter

The submission shall have a cover letter providing the following information described in §807.87 (Information required in a premarket notification submission):

1. the trade or proprietary name;

2. common names: Select the appropriate name from the following:

   a. Nonsterile or sterile surgical drape

   b. Surgical towel or operating room towel

   c. Nonsterile or sterile surgical gowns

3. classification names: Select the appropriate name from the following:

   a. Surgical drape and drape accessories

   b. Surgical apparel

4. the establishment registration number, if applicable, of the sponsor, owner or operator submitting the premarket notification;

5. the appropriate class, panel and procode from the following:

Class: II
Panel: 79
Procodes: KKX - Surgical drapes
FYA - Surgical gowns
FYC - Isolation gown
FPH - Operating room gowns

6. a statement explaining the purpose of the submission (e.g., new device, significant modification of device previously found equivalent (new intended use, material, or manufacturing process, etc.)

For devices that are being modified, refer to §807.87(g) for additional requirements. The change may require some or all of the information needed for a new device. Please supply the previous 510 (k) number(s), if applicable.

7. a brief statement indicating the device is similar to and/or different from other products of comparable type in commercial distribution; and

8. the name and phone number of a U.S. contact person, if available.

B. Table of Contents

The 510(k) shall include a table of contents noting section titles and pages. Each section shall be separated and begin with a section contents page if the section consists of several parts.

C. Labels and Labeling

1. The submission should contain proposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for use. Labels include the information affixed directly to the device and its packaging.

2. The labeling must meet the requirements of 21 CFR Part 801 as it relates to a determination of intended use. ODE will therefore concentrate on the following:

Subpart A, §801.4 and §801.5, related to intended uses and adequate directions for use; and

Subpart B, §801.109 and §801.116, related to prescription devices and commonly known directions.

Other portions of labeling requirements are deferred for review to CDRH/OC Promotion and Advertising Policy Staff.

3. Labeling for surgical gowns and surgical drapes shall contain the following, as applicable :

   a. the contents of the package, i.e., surgical gowns, isolation gowns, abdominal drapes or surgical drapes;

   b. the size (S,M,L,XL) for gowns or measurements for drapes;

   c. quantity and the conditions of use, i.e., reusable, disposable/single use;

   d. for sterile, single use gowns and drapes, the word "Sterile", and the statement, "Unless Package is Opened or Damaged";

   e. the manufacturer lot and batch numbers;

   f. for gowns and/or drapes offered nonsterile and/or reusable to the end user, the label shall contain instructions on how to reprocess the device including laundering and sterilization information, the number of reprocessings the gown/drape can withstand and a system for keeping track of reuse cycles; and

   g. any specific warning/caution statements, i.e., "Do not use near flammable anesthesia gases", or "Does not meet NFPA standards."

D. Standards

Appropriate or relevant industry or regulatory standards which the gown or drape meets should be referenced, including the year of the standards publication. The applicant may certify that the device meets the stated standard. The applicant then is obliged to meet the standard and maintain documentation of testing showing that the device meets the standard. Certification of meeting a specific standard may reduce the data requirements for the 510(k) submission.

Listed below are some relevant standards used in determining the barrier performance and safe use of gowns and drapes;

1. NFPA Standards - Standards for the Use of Inhalation Anesthetics.

2. ASTM ES-21-1992, Standard Test Method for Resistance of Protective Clothing Materials to Synthetic Blood.

3. ASTM ES-22-1992, Test Method for Resistance of Protective Clothing Materials to Penetration by Bloodborne Pathogens Using Viral Penetration as a Test System.

4. ASTM D737-75, Air Permeability.

5. AATCC Test Method 127-1989, Water Resistance: Hydrostatic Pressure

Test (water resistance claims).

6. AATCC Test Method 61-1989, Colorfastness to Laundering, Home and Commercial: Accelerated.

7. ASTM D1424, Elemendorf Tear.

8. ASTM D1682, Grab Tensile/Elongation.

E. Device Description

The applicant must submit a complete description of the device, including all models, styles and variations.

1. Provide a description of the device in sufficient detail to facilitate the evaluation of the device (e.g., photographs, detailed drawings). Drawings of surgical gowns should show barrier features and/or specifications in critical areas of the gown (e.g., cuffs and seams, the thoracic region of the gown, and sleeve areas).

2. Provide a clear description of the intended use(s) of the device.

3. Provide the specifications for the device(s). The applicant may refer to relevant standards.

   a. Physical Specifications

      (1) weave, thread count, weight per square yard or thickness, as applicable

      (2) sizes (S,M,L,XL)

      (3) resistance to blood and liquid penetration

      (4) resistance to tears and punctures

      (5) features for safe use in the operating room environment, i.e.,lint free, free of toxic ingredients and nonfast dyes

      (6) fire protection

   b. Mechanical Specifications

      (1) strength (tensile, grab, burst)

      (2) durability - number of times the device can be processed (laundered and sterilized) and meet specifications using the sterilization method indicated in the labeling

c. Biological Specifications

(1) Materials and colors used in the finished gown/drape must be biocompatible in accordance with the Tripartite Biocompatibility Guidance or ISO 194. The materials must be biocompatible within the conditions of patient/user exposure. These devices are categorized under the guidance as External, Breached or Compromised Surface, Short-Term.

4. Provide a complete listing of all materials used in fabricating the device, i.e., colors, dyes, fabrics.

F. Descriptive Comparison to a Legally Marketed Device

Identify a legally marketed device to which substantial equivalence is claimed. If possible, provide the 510(k) numbers. More than one device can be listed, but the device(s) chosen should be as close in intended use and technology to the new device as possible. Provide the information noted below to show how the new device is both similar to or different from the legally marketed device. Side by side comparisons, whenever possible, are desirable (see Attachment 1). Indicate how any differences may affect safety and effectiveness.

1. Provide labeling (labels, instructions for use, promotional material) for the legally marketed device(s) to which substantial equivalence is claimed. To facilitate comparison, also include clear photographs, or other representations of the legally marketed device(s), unless the labeling has ample information.

2. Compare and contrast the intended use for the new device to the predicate.

3. Compare all materials used to fabricate the device. The precise materials of the new device, and if possible, the predicate should be identified to the extent possible.

4. Compare physical, mechanical, and biological specifications and performance data.

G. Performance Data Supporting Substantial Equivalence

In many cases descriptive data alone will be sufficient to establish equivalence. However, comparisons of performance of the new device to a legally marketed device may be necessary. When requested, provide the protocols and results of specified tests needed to establish equivalence. If the stated test is a standard method that specifically addresses the performance criterion, then the applicant may reference the method and certify that the device will meet the criterion. Data need not be submitted in this instance.

The studies should be well designed to meet the stated objectives. This will include rigorous attention to: statistical elements (hypotheses, test statistic, analyses, sample size and sampling, power, etc), inclusion/exclusion criteria, controls, minimization of bias, test parameters (endpoints), follow up, evaluation criteria, etc. Some of the above points may overlap. Ample reference material exists on study design and methods upon which the applicant may rely if the method is not specified in the guidance (e.g., biocompatibility).

The submission should provide test data which demonstrates that the surgical gown/drape is made of material that is an effective barrier for minimizing the passage of microorganisms between nonsterile and sterile areas. Provide the protocols and the results of specified tests that are needed to establish equivalence.

1. Biocompatibility

   Submit a certification that either (1) the identical materials have been used in other legally marketed devices used under the same use conditions, or (2) provide documentation attesting to the biocompatibility of the component materials in the finished product according to the 1987 Tripartite Biocompatibility Guidance for Medical Devices and/or 1992 draft ISO 194 standard (Biological testing of Medical and Dental Materials and Devices).

   Biocompatibility test data may be required for colors that are not listed in FDA regulations, or are not used in other legally marketed devices for a similar intended use.

2. Comparative Claims

   Additional data may be needed for comparative claims that are unique or not based upon a standard that the applicant has certified the device meets.

3. Unique Designs

   Additional data may be needed to support designs that are significantly different from traditional designs and are not encompassed by standards to which the applicant can reference.

H. Sterility Information

For a device sold sterile, provide the following information as detailed in the ODE Blue Book Memorandum #K90-1.

1. Sterilization method that will be used.

2. A description of the method that will be used to validate the sterilization cycle, but not the validation data itself. Reference to a standard method (e.g., AAMI Radiation Standard) usually is sufficient.

3. The sterility assurance level (SAL) for the device which the firm intends to meet. An SAL of 10^{-6} is required for surgical drapes and surgical gowns which are to be used during surgical procedures.

4. A description of the packaging to maintain the device's sterility (this is not to include packaging integrity testing data).

5. If sterilization involves EtO, the maximum levels of residues of ethylene oxide, ethylene chlorohydrin, and ethylene glycol which remain on the device. The levels should be consistent with the draft Federal Register Notice on EtO limits.[1]

6. The radiation dose, if radiation sterilization will be used, and if it has been determined. Otherwise, amend the 510(k) file at FDA when the dose has been determined.

References

1. FDA Proposed Rule, 43 FR 27482 (June 23, 1978), Maximum Residue Limits for Ethylene Oxide, Ethylene Chlorohydrin, and Ethylene Glycol.

I. SMDA Requirements

All persons submitting a 510 (k) must include either a summary of safety and effectiveness information in the 510 (k) upon which an equivalence determination could be based OR a statement that safety and effectiveness information about the [device name] will be made available to any interested person upon request. Safety and effectiveness information refers to adverse safety and effectiveness information, or descriptive information about the new and predicate devices, or performances/clinical testing information.

If the summary option is selected, it should be included on a separate page and identified as the Summary of Safety and Effectiveness for [device name].

If the statement option is selected, do not include the word "summary" in the statement.

The content and format of this information is specified in 57 FR No. 82, Tuesday, April 28, 1992, page 18062.

J. Contacts and Addresses

General questions regarding the submission of premarket applications should be directed to the Division of Small Manufacturers Assistance at (800) 638-2041.

Questions regarding this guidance document should be directed to the following address:

FDA
Division of General and Restorative Devices (HFZ-410)
Infection Control Devices Branch
1390 Piccard Dr.
Rockville, MD. 20850
(301) 594-1307

K. Reviewer's Checklist

510(k) Number &
Device Name _____

Sponsor/Company _____

Date: _____ Reviewer: _____

ITEM		PRESENT Yes	PRESENT No	NEEDED (Y/N/?)
I.	Cover Letter			
	Proprietary name	—	—	—
	Common name	—	—	—
	Classification name	—	—	—
	Establishment Registration	—	—	—
	Procode(s)	—	—	—
	Purpose of submission	—	—	—
	Statement that the device is similar to and/or different from other product	—	—	—
	Contact person	—	—	—
II.	Labels and Labeling			
	Proposed labels & labeling	—	—	—
	Labeling requirements	—	—	—
	Package labeling	—	—	—
III.	Standards			
	Standards listed	—	—	—
IV.	Device Description			
	Description of device	—	—	—
	Intended use(s)	—	—	—

	Specifications	—	—	—
V.	Descriptive Comparison to a Predicate			
	Labeling	—	—	—
	Intended use	—	—	—
	Materials used	—	—	—
	Performance	—	—	—
VI.	Performance Data Supporting Substantial Equivalence			
	Data provided	—	—	—
VII.	Sterility Information			
	Sterile/non-sterile	—	—	—
	Sterilization method	—	—	—
	Validation method	—	—	—
	Sterility Assurance Level	—	—	—
	Packaging information	—	—	—
	EtO residues	—	—	—
	Radiation dose	—	—	—
VIII.	SMDA Requirements			
	510(k) summary	—	—	—
	510(k) statement	—	—	—

L. COMPARISON TABLE

Feature	New Device	Predicate
Material Composition		
Weave		
Weight per yard square		
Thickness		
Strength		
Lint level		
BARRIER PERFORMANCE TESTS RESULTS:		
ASTM ES-21-1992		
ASTM ES-22-1992		
ASTM D1424		
ASTM D1682		
Flammability (NFPA 702)		
Sterilization Method		
Colorants		
Colorfastness		
Use Life		

III. Premarket Notifications for Kits

In a 510(k) submission for a kit, i.e., a package consisting of at least one medical device (such as surgical gowns or surgical drapes) and additional devices (such as surgeon's gloves), drugs, or biologics as other components, the applicant must provide the following:

1. Include a complete and specific listing of all components of the kit(s).

2. Certifications:

   (a) I certify that the medical device components of my kit listed on page(s) [SUBMITTER PROVIDE PAGE NUMBERS] are either (1) legally marketed preamendments devices, (2) exempt from premarket notification (consistent with the exemption criteria described in the classification regulations and the limitations of exemptions from Section 510(k) of the act (e.g., 21 CFR 862.9), or (3) have been found to be substantially equivalent through the premarket notification process for the use(s) for which the kit is intended (i.e., not claiming or causing a new use for the component(s)).

   (b) I further certify that I purchase the device components in finished form, i.e., they are packaged, labeled, etc., consistent with their preamendments, exemption, or premarket notification criteria and status. All purchased drug or biologic components are also packaged and labeled consistent with their approval or licensing.

   If you cannot make certification statement (a) for each device component of your kit, you must itemize the components without preamendments, exemption, or premarket notification status. You must also supply adequate information so that FDA can evaluate the equivalence of these components of your kit. This information may be the same information needed for a separate 510(k) for each component.

   If you cannot make certification statement (b), then identify the components purchased in unfinished form, e.g., packaged in bulk (not final packaged and labeled in separate units).

3. Clearly identify in the list of kit components any that are drugs and biologics. For example, state next to the item that it is a drug or a biologic.

4. Describe how the kit is assembled and processed into finished form for purchase (e.g., the components are taken out of the finished product or bulk packaging, component X is individually sterilized, all the components are then placed on a tray, the kit is wrapped, but not sterilized prior to shipment).

If there is any repackaging or reprocessing of a separate component, then you must provide details on the repackaging or processing and an analysis of the effect on the component. This may require testing. For example, for (re)sterilized devices conduct a validation study and provide data in accordance with the ODE Sterility Blue Book Memorandum. The processing of the final kit is also important. You must evaluate whether the final processing for the kit as a whole affects the safety or effectiveness of any of the kit components.

5. The 510(k) should include all labels and labeling for the kit. A kit label alone may suffice for all components only if the label consolidates the required information typically found in labeling for each individual kit component when sold separately in final form. A component may require specific labeling, such as a package insert, when adequate directions for use (precautions, warnings, etc.) are required. It is important to examine the labeling for the individual components sold separately versus the labeling provided for the kit. Verify that the labeling is adequate or enclose additional labeling in the kit, as needed.

6. The items above identify labeling and processing issues which may affect the regulatory status, or safety and effectiveness of the kit. If you are aware of any other factor which may impact upon the status of your kit, then please bring it to our attention so that we may consider it in our evaluation.