Guidance for Industry

Latex Condoms for Men

Information for 510(k) Premarket Notifications: Use of Consensus Standards for Abbreviated Submissions

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U.S. Department Of Health And Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Obstetric and Gynecology Devices Branch
Division of Reproductive, Abdominal, Ear, Nose and Throat, and Radiological Devices
Office of Device Evaluation

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to http://www.regulations.gov. Submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance, contact Susan Andrews at 870-543-4653 x4653, or susan.andrews@fda.hhs.gov

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Latex Condoms for Men
Information for 510(k) Premarket Notifications:
Use of Consensus Standards for Abbreviated Submissions

Section 510(k) of the Act and the implementing regulation, 21 CFR Part 807, require persons who intend to market a new device to submit a premarket notification containing information that enables FDA to determine whether the new device is substantially equivalent within the meaning of Section 513(i) of the Act to a legally marketed device that does not require premarket approval. Unless exempted from premarket notification requirements, persons may not market a new device under Section 510(k) of the Act, unless they receive a substantial equivalence order from FDA or an order reclassifying the device into Class I or Class II (section 513(i) of the Act). Male condoms are classified as Class II devices under 21 CFR §884.5300 and §884.5310 (Condom with spermicidal lubricant) and are not exempted from 510(k) requirements, therefore, a 510(k) premarket notification must be cleared by order of FDA before a new male condom, or one that has been significantly changed or modified, is introduced into interstate commerce.

A person required to submit a 510(k) premarket notification must provide information as required by the statute and regulations to allow the Center to make an appropriate decision regarding the clearance of the submission.

The Center believes that conformance with recognized consensus standards can provide a reasonable assurance of safety and/or effectiveness for many aspects of medical devices, including Male Latex Condoms. A 510(k) that contains a declaration of conformity to recognized consensus standards, as discussed below, will, in most cases, eliminate the need to review the actual test data for those aspects of the device addressed by the standards. This, however, does not affect the Center's ability to obtain any information authorized by the statute or regulations. Conformance with recognized consensus standards in and of itself may not always be a sufficient basis for regulatory decisions. For example, a specific device and/or intended use may raise safety or effectiveness issues not addressed by any recognized consensus standard, or a specific FDA regulation may require additional information beyond what conformity to recognized consensus standards provide. Under such circumstances, conformity with recognized standards will not satisfy all requirements for marketing the latex condom in the United States.

The Center for Devices and Radiological Health has recognized and will use consensus standards pursuant to the Food and Drug Administration Modernization Act of 1997 (P.L. 105-115), which amends section 514 of the Food, Drug, and Cosmetic Act (21 U.S.C. 514(c)). FDA has recognized voluntary consensus standards for Latex Condoms for Men, and other relevant standards may also be applicable to the submission of a 510(k) for a latex condom, *e.g.*, ISO 10993. A list of recognized standards is maintained on the CDRH website and is updated at least annually. Other recognized standards may be applicable for latex condoms and **manufacturers have the right to make a declaration of conformity to any listed standard.** *[FDA Guidance on the Recognition and Use of Consensus Standards*, February 19, 1998, q.v.]

Building on FDA's recognition of the ASTM voluntary consensus standard for condoms and the ISO voluntary consensus standard for biological evaluation of medical devices, this guidance document provides an outline for a 510(k) premarket notification that incorporates a declaration of conformance with these standards. When the declaration is combined in a 510(k) which is complete and accurate, it can serve as the basis for an FDA finding of substantial equivalence for a Natural Rubber Latex (NRL) Condom. (Other criteria exist for blends and non-NRL Male Condoms and for Female Condoms.)

This guidance document represents the agency's current thinking on the use of consensus standards for abbreviated submissions for 510(k) Premarket notifications for latex condoms for men. It does not create or confer any 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.

<< Cover Letter >>

[Date of Submission]

Food and Drug Administration
Center Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, MD 20850

Re: Abbreviated 510(k) Notification
***[Brand Name]* Male Latex Condom**

Dear Sir or Madam:

This submission is being made in compliance with Section 510(k) of the Food, Drug and Cosmetic Act as amended by the Medical Device Amendments of 1976, the Safe Medical Devices Act of 1990 and the Food and Drug Administration Modernization Act of 1997, and the Office of Device Evaluation guidance for Abbreviated 510(k) requirements for a male latex condom. The enclosed information is being submitted for the *[Brand Name]* Male Latex Condom, which is made from Natural Rubber Latex. Two copies of this Premarket Notification are being submitted in accordance with 21 CFR 807.

The purpose of this submission is to notify FDA, in accordance with the 510(k) provisions of the Act, of our intent to introduce this *[new product, the…* /or/ *modification of the currently marketed] [Brand Name]* Male Condom into commercial distribution.

If you have any questions regarding this submission, please telephone *[contact person's name]* at *[(area) phone number]*.

Sincerely yours,

[*signature]*

[Name]
[Title]

PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT

[Refer to §807.85(j)]

I certify, in my capacity as *[Title]*, that I believe, to the best of my knowledge, that all data and information submitted in this 510(k) Premarket Notification Submission is truthful and accurate and that no material fact has been omitted.

[signature]
……
[Name]
[Title]

[date]
……
Date

I. GENERAL INFORMATION

A. Submitter's Name and Address
[Company Name]
[P.O. Box & Street Address]
[City, State, ZIP]

B. Contact Person
[Name]
[Title]
[Phone]
[Fax]

C. Establishment Registration Number of Submitter
[Number]

D. Contract Manufacturing Facility
[Company Name & Address]
Establishment Registration: *[Number]*

E. Device Name
Proprietary Name:
Common Name:
Classification Name:

F. Device Classification
Class II §884.5300 and/or §884.5310 (Condom with spermicidal lubricant)

G. Action Taken to Comply with Section 514 of the Act
The Agency has recognized the ASTM Standard Specifications for Rubber Contraceptives (Condoms), D3492, and the ISO standard 10993: Biological Evaluation of Medical Devices. Conformance or variance with these standards is described on the following pages.

H. Reason for 510(k) Submission
- ❑ Initial Product Introduction
- ❑ New Model for Product-line Extension
- ❑ Initial Import into the USA
- ❑ Other (Include in Part IV an explanation referenced to Part I.H.)

I. Predicate Device
[Brand Name of Predicate Device]
[Company Name]
510(k) Document Control Number *[K######]*

NOTE: *Provide the information required by 21 CFR §807.92, Content and format for a 510(k) summary (Option 1), below*
OR
the 510(k) Statement (Option 2) on the next page.

II. 510(k) SUMMARY (Option 1)

[Refer to 21 CFR §807.92]

Submitted by: [*Company*]
[*Division*]
[*P.O. Box / Street Address*]
[*City, State Zip*]
[*Phone*]

Contact Person: [*Individual's Name*]

Date Prepared: [*Date*]

Proprietary Name: [*Brand Name of Condom*]

Common Name: Latex Condom

Classification Name: Condom (21 CFR §884.5300)
and / or
Condom with Spermicidal Lubricant (21 CFR §884.5310)

Predicate Device: Latex Lubricated Condom
510(k) #K[######]
and / or
Latex Condom with Spermicidal Lubricant
510(k) #K[######]

Description of the Device: This condom is made of a natural rubber latex sheath, which completely covers the penis with a closely fitted membrane. This condom [*include a brief description of the condom, such as, a straight-walled, nipple-end, nominal length, nominal width, nominal thickness, etc*].

Intended Use of the Device: This latex condom has the same intended use as the predicate condom. The condom is used for contraception and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted diseases.)

Technological Characteristics: [*Indicate whether the condom has the same technological characteristics as the predicate condom identified above. Indicate that the design is in conformance with ASTM Latex Condom Standard D3492 and that the condom is made of natural rubber latex. Summarize the similarities and differences of the features and technological characteristics of the condom in comparison to the predicate condom.*]

II. 510(k) STATEMENT (Option 2)

[Refer to §807.93]

I certify that, in my capacity as (the position held in company by person required to submit the premarket notification, preferably the official correspondent in the firm), of (company name), I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.

.

Certified: _____*[Signed]*_____

_____*[Date]*_____

III. DECLARATION of CONFORMANCE with CONSENSUS STANDARDS

A. The condom intended to be introduced conforms in all respects with the requirements of the current edition of ASTM* Standard Specification for Rubber Contraceptives (Male Condoms), D3492, except as noted "at variance":

Requirement*	SO STIPULATED †	AT VARIANCE ‡
1. Manufactured from good quality natural rubber latex.(ammoniated), conforming to Specification ASTM D 1076-97	1. ☐	☐
2. Meets criteria that toxic, sensitizing, locally irritating, or otherwise harmful substances are not released or liberated	2. ☐	☐
3. Minimum length is 160 mm	3. ☐	☐
4. Maximum width is 54 mm	4. ☐	☐
5. Minimum thickness is 0.03 mm	5. ☐	☐
6. Air Burst Test Pressure	6. ☐	☐
7. Air Burst Test Volume	7. ☐	☐
8. Leakage AQL	8. ☐	☐
9. Package integrity AQL	9. ☐	☐

B. The condom intended to be introduced has been tested in conformance with the following test methods of ISO 10993 Biological Evaluation of Medical Devices and ODE Guidance Memorandum G95-1 dated May 1, 1995, for a Device in Contact for 24 hours or less with a Skin/Mucosal Membrane Surface, except as noted "at variance". When evaluated according to this standard, the condom is not toxic (local or systemic), sensitizing, locally irritating or otherwise harmful.

Requirement*	SO STIPULATED †	AT VARIANCE ‡
1. ISO 10993-5 — Cytotoxicity	1. ☐	☐
2. ISO 10993-10 — Irritation and Sensitization	2. ☐	☐
3. ISO 10993-11 — Systemic Toxicity	3. ☐	☐
4. ISO 10993-12 — Sample Preparation and Reference Materials	4. ☐	☐

The ISO 10993 standard describes test methods, but does not specify performance limits for each test. Therefore, data summaries and results of the above safety testing are included in Part IV.

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* ASTM — American Society for Testing and Materials, 100 Barr Harbor Drive, West Conshohocken, PA 19428; (610) 832-9500. Refer to full text of ASTM D3492 for the specific requirements that apply.

† Certifying signature required on next page of this Part.

‡ Include (under a separate section, identified with the item number) information, data, and analyses appropriately describing and explaining variance from standard; include rationale for variance and justification why this variance does not have a material impact on the substantial equivalence of the condom.

III. DECLARATION of CONFORMANCE with CONSENSUS STANDARDS

(continued)

C. This device is certified to comply with the voluntary standards as contained in ASTM D3492– *[insert edition date]* and ISO 10993– *[insert edition date]*, as specified and so stipulated above, unless and where specifically so indicated to be at variance with the standard specification, in which case information, data, and analysis, or justification for non-applicability, are provided to fully describe the variance and its impact on the device and to justify said variance.

[signature]

[Name]
[Title]

[Date]

Date

When there is a third-party certifying laboratory or certification body, provide the names and addresses and a reference to any accreditation of each laboratory. Certification statements should also be included.

IV. DESCRIPTION OF DEVICE

A. Description of the Device: This condom is made of a natural rubber latex sheath, which completely covers the penis with a closely fitted membrane. This condom [i*nclude a diagram(s) and a brief description of the condom, such as, a straight-walled, nipple-end, nominal length, nominal width, nominal thickness, dusting powder, lubricant systems, and other specifications. If a color additive is used, include a citation to the FDA Color Listing Regulation for the color and the Color Index Number*]. See example, Tabs 1 and 2.

B. Proprietary and Confidential Compounded Latex Formulation: [Provide a listing of the component ingredients and the range of quantities used in the preparation of the compounded latex.] See example, Tab 2.

C. Summary Reports of Safety Testing Results: [*Provide a summary of the results obtained from the cytotoxicity, irritation and sensitization, and systemic toxicity testing as stipulated under Part III B above. See ODE Guidance Memoranda G95-1, May 1, 1995.*]

V. STATEMENT OF SUBSTANTIAL EQUIVALENCE

Indicate whether the condom has the same intended use and technological characteristics as the predicate condom. Summarize the similarities and differences of the features and technological characteristics of the condom in comparison to the predicate condom.

VI. LABELS, LABELING AND ADVERTISEMENTS

Provide proposed labels, labeling and advertisements sufficient to describe the device, its intended use, and the directions for use. (21 CFR 807.87(e)) For overall labeling guidance, manufacturers are encouraged to consult with FDA's manual "Labeling: Regulatory Requirements for Medical Devices," (HHS Publication FDA 89-4203). (Also see Title 21 CFR §801, §801.435 and §801.437.) Labeling for latex condoms should include but not be limited to the following:

A. Statement of Identity and Intended Use

1. The principal display panel as defined in 21 CFR 801.60 and primary package (individual condom packet) should identify the device as a male **LATEX** condom.

2. The principal display panel and primary package should identify the intended use for male condoms, i.e., contraception.

3. The principal display panel, and primary package (individual condom packet) should also include the following statement:

   If used properly, latex condoms will help to reduce the risk of transmission of HIV infection (AIDS) and many other sexually transmitted diseases.

   The following expanded statement should be added to the package insert, directions for use:

   If used properly, latex condoms will help to reduce the risk of transmission of HIV infection (AIDS) and many other sexually transmitted diseases, including chlamydia infections, genital herpes, genital warts, gonorrhea, hepatitis B, and syphilis.

4. Special labeling is required for condoms lubricated with a spermicidal lubricant. The principal display panel, primary package and any package insert must prominently and conspicuously bear a specific contraceptive effectiveness cautionary provision:

   This product combines a latex condom and a spermicidal lubricant. The spermicide, nonoxynol-9, reduces the number of active sperm, thereby decreasing the risk of pregnancy if some semen spills or seeps outside the condom. However, the extent of decreased risk has not been established. This condom should not be used as a substitute for the combined use of a vaginal spermicide and a condom.

B. The package insert for latex condoms should contain a contraceptive effectiveness table with pregnancy rates for all drug and device contraceptives. This information will enable contraceptive users to compare their contraceptive to alternatives and make appropriate choices. FDA has developed such a table entitled "Pregnancy Rates for Birth Control Methods," that can be used for this purpose. This table is the result of an intra-agency effort that included focus studies funded by FDAs Office of Womens Health. Data for this table comes from Contraceptive Technology, 17th ed., Hatcher et al., and will be updated periodically as new data becomes available.

See ODE guidance entitled "Uniform Contraceptive Labeling: Guidance To Industry."

VI. LABELS, LABELING AND ADVERTISEMENTS
(continued)

C. The Center has issued specific guidance that established the intended use and suggested directions for use for male latex condoms. This guidance provides acceptable and appropriate labeling. The following are suggested precautions and directions for use:

Precautions

- **Use a new condom every time you have sexual intercourse or other acts between partners that involve contact with the penis.**
- **Do Not Reuse Condoms.**
- **Store condoms in a cool, dry place.**
- **If the rubber material is sticky or brittle or obviously damaged, do not use it.**
- **If a lubricant is wanted, use water-based lubricants such as [name of product]. *DO NOT USE OIL-BASED LUBRICANTS*, such as those made with petroleum jelly (e.g., Vaseline®), mineral oil, vegetable oil, or cold cream, as these may damage the condom.**

Directions for Use

- **Put the condom on after the penis is fully erect and *before* intimate contact. Lesions, pre-ejaculate secretions, semen, vaginal secretions, saliva, urine, and feces can all transmit disease organisms.**
- **Place the condom on the head of the penis and unroll or pull it all the way to the base.**
- **Leave an empty space at the end of the condom to collect semen. Remove any air remaining in the tip of the condom by gently pressing the air out toward the base of the penis.**
- **After ejaculation and while the penis is still erect, hold onto the rim of the condom so that the condom does not slip off as the penis is carefully withdrawn.**

D. The retail and primary package (individual condom packet) must include an expiration date. (See 21 CFR §801.435, User labeling for latex condom, effective March 25, 1998.)

E. On September 30, 1997, FDA published a Final Rule (62 FR 51021-51030, 1997), codified at 21 CFR 801.437, which will require all medical device products composed of or containing, natural rubber latex and which contact humans, such as latex condoms, to bear the following statement in bold print on the device labeling, in conformance with Section 502(c) of the Act:

CAUTION: THIS PRODUCT CONTAINS NATURAL RUBBER LATEX WHICH MAY CAUSE ALLERGIC REACTIONS

This statement must appear on all device labels, and other labeling, and shall appear on the principal display panel of the device packaging, the outside package, container or wrapper, and the immediate device package, container or wrapper. This final rule has an effective date of September 30, 1998. This labeling requirement is considered necessary because devices composed of, or containing, natural rubber latex, pose a significant health risk to some individuals. (See also, FDA's March 29, 1991, FDA Medical Alert, Allergic Reactions to Latex-Containing Medical Devices. MDA91-1.)

VII. INDICATIONS FOR USE STATEMENT

510(k) Number: (if known)

Device Name: [*Brand Name*] Male Natural Rubber Latex Condom

Indications For Use: The [*Brand Name*] condom is used for contraception and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted diseases).

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

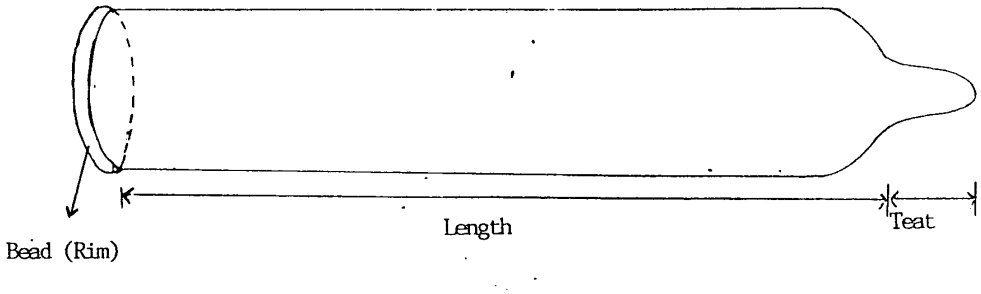
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use_____

(Per 21 CFR §801.109)

Tab 1 - Device Description

Provide a diagram (or diagrams) of the subject latex condom. The diagram should show key dimensions, as well as relevant contours.



Provide all relevant product specifications that adequately characterize the condom. Given below is an example of how this information should be given.

Typical (Average) Product Characteristics

- Nominal length (mm)
- Nominal width (mm)
- Nominal thickness (mm)
- Air burst test pressure
- Air burst test volume
- Materials of the primary package (individual condom packet)
- Lubricant system (include viscosity)

Tab 2 - Compounded Latex Formulation

Provide a complete summary of the compounded latex formulation and other materials used in the manufacture of the condom. Given below is an example to illustrate how this information should be given.

TABLE 1 - Compounded Latex Formulation Summary

GENERIC NAME & CHEMICAL COMPOSITION	CAS NO	PERCENTAGE RANGE PPH $_{LATEX}$	FUNCTION
Natural Rubber Latex (cis-1,4-polyisoprene)		100.00	
Diisopropyl xanthogen polysulfide		--	Vulcanizing agent (cross-linking)
Sulfur		--	Vulcanizing agent (cross-linking)
Zinc Oxide		--	Activator
Zinc-N-diethyl-dithio-carbomate		--	Accelerator
Zinc-N-dibutyl-dithio-carbomate		--	Accelerator
Potassium Hydroxide		--	Stabilizing agent
Sodium lauryl sulfate		--	Emulsifier
Naphthalene sulfonic acid-formaldehyde condensate, sodium salt		--	Emulsifier
Ammonia			Preservative
Formaldehyde			Preservative
		--	Antioxidant
		--	Anti-ozonants

TABLE 2 - Compounded Formulation Condom Additives

GENERIC NAME & CHEMICAL COMPOSITION	SUPPLIER	CAS NO.	AMOUNT (MG)
DUSTING AGENTS			
U.S.P. Corn Starch			
LUBRICANTS			
Silicone (polydimethylsiloxane)			
Nonoxynol-9			

TABLE 3 - Condom Composition Summary - Colors

COLOR	PIGMENT	C.I. NO.	CAS REG. NO.	21 CFR CITATION	AMOUNT PPH $_{LATEX}$
Red	C.I. Pigment Red 48:2 Permanent Carmine	C.I.#12490		73.100	
Blue	C.I. Pigment Blue 15:2/Copper Phthalocyanine Blue	C.I. #74160	CAS Reg No.147-14-8	178.3297(e)	
Green	C.I. Pigment Green 7/Polychloro Copper Phthalocyanine Green	C.I. #74260	CAS Reg No.1328-53-6	178.3297(e)	
Yellow	C.I. Pigment Yellow 74 Azo Yellow	C.I. #11741	CAS Reg No.6358-31-2	177.2600	