



U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER: (cwf)
FOLDER: K895640 - 66 pages
COMPANY: CARTER-WALLACE, INC. (CARTWALL)
PRODUCT: CONDOM (HIS)
SUMMARY: Product: MAGNUM PLUS LATEX CONDOM W/SPERMICIDAL LUBRICANT
DATE REQUESTED: Aug 26, 2016
DATE PRINTED: Aug 26, 2016

Note: Printed



K895640

Jones, Edwena

From: Andrews, Sharon M
Sent: Tuesday, September 11, 2012 9:15 PM
To: Jones, Edwena
Cc: Blyskun, Elaine
Subject: RE: updating Device Listing

Hi Edwena,

I looked up both K912901 and K895640 in IMAGE, and the condoms cleared in both submissions contain N-9. The SE letters for both devices also include the regulation number for condoms with N-9 (21 CFR 884.5310). Therefore, I agree that LTZ (condom with nonoxynol-9) should be added as a product code for both 510(k)s.

Please let me know if you need anything else.

Thank you.

Sharon

From: Jones, Edwena
Sent: Monday, September 10, 2012 10:24 AM
To: Andrews, Sharon M
Subject: FW: updating Device Listing

Hi Sharon,

The sponsor is inquiring about a product code for their cleared product. If you agree that LTZ should be added please let me know. I will update the database, since the clearance was prior to adding the product codes to the SE letters, we will not have to generate a letter.

Please let me know if you need any additional assistance.

Thank you
 Edwena

From: Vescovi, Karen [<mailto:Karen.Vescovi@churchdwright.com>]
Sent: Thursday, July 12, 2012 3:07 PM
To: CDRH Registration and Listing; Jones, Edwena
Subject: RE: updating Device Listing

Thank you, Doug.

Dear Edwena Jones, please see e-mail chain below for history of request.

We have two 510(k)s that the products are classified as HIS (latex condom) when K912901 should also have included the product code LTZ for a Latex Condom with Spermicidal Lubricant, this 510(k) was cleared for both. The other 510(k) K895640 was submitted and cleared for a Latex Condom with Spermicidal Lubricant but is classified with product code HIS.

I'm not sure if this is just an oversight or if at that time all Condoms were classified as "HIS", just as previously only the product codes were listed not the individual product. Please advise if this can be adjusted so we can update our listing for these product.

Regards,
 Karen

Karen Vescovi
 Regulatory Specialist
 Church & Dwight Co., Inc.
 469 North Harrison Street
 Princeton, NJ 08543

(609) 279-7715 phone
 (609) 497-7179 fax
karen.vescovi@churchdwright.com

From: CDRH Registration and Listing [<mailto:reglist@CDRH.FDA.GOV>]
Sent: Thursday, July 12, 2012 2:43 PM
To: Vescovi, Karen; CDRH Registration and Listing
Subject: RE: updating Device Listing

9/21/2012

Karen Vescovi,

If you feel that a product code has been omitted from your 510K, please contact Edwena Jones at the Office of Device Evaluation at Edwena.Jones@fda.hhs.gov

The Medical Device Registration and Listing Program is separate from the 510(k) program. I would recommend that you contact the FDA Center for Devices and Radiological Health's Division of Small Manufacturers, International and Consumer Assistance (DSMICA) for help in resolving this matter. They can be reached by phone at (800) 638-2041 or 301-796-7100, or by email at dsmica@fda.hhs.gov.

Additional information can be found at the 510(k) website at:
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm>.

Please note: General information regarding Registration and Listing can be found on our web site:
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/default.htm>

This is an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

Thank you,
Doug Zveare

From: Vescovi, Karen [<mailto:Karen.Vescovi@churchdwright.com>]
Sent: Thursday, July 12, 2012 1:48 PM
To: CDRH Registration and Listing
Subject: RE: updating Device Listing

Hi Doug, thank you for your expedited response.

I understand that you cannot just "add" a product code but the 510(k) associated with this product was cleared under 21 CFR 884.5300 and 21 FR 884.5310 for latex condom with both lubricated and spermicidal versions, I have attached the FDA Clearance Letter dated February 3, 1992.

There also seems to be a mistake with another 510(k) K895640, for Magnum Plus Latex Condom with Spermicidal Silicone lubricant, cleared January 23, 1990 according to FDA website search it also is not recorded as a spermicidal LTZ product code it too is listed under HIS 21 CFR 884.5300.

Any help is greatly appreciated, as K912901 is for both HIS and LTZ and K895640 is a 510(k) for a Latex Condom with Spermicidal Lubricant..

Regards,
Karen

Karen Vescovi
Regulatory Specialist
Church & Dwight Co., Inc.
469 North Harrison Street
Princeton, NJ 08543

(609) 279-7715 phone
(609) 497-7179 fax
karen.vescovi@churchdwright.com

From: CDRH Registration and Listing [<mailto:reglist@CDRH.FDA.GOV>]
Sent: Thursday, July 12, 2012 1:21 PM
To: Vescovi, Karen; CDRH Registration and Listing
Subject: RE: updating Device Listing

Karen Vescovi,

Product code LTZ is a 510(k) submission. If you wish to list product code LTZ you will need to submit a 510(k) and wait for its approval. You cannot add this product code to another 510(k) listing. When a 510(k) is approved FDA assigns the appropriate product code(s). The assigned product code(s) may not be changed or new product codes added.

Please note: General information regarding Registration and Listing can be found on our web site:
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/default.htm>

This is an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

Thank you,

Doug Zveare

From: Vescovi, Karen [<mailto:Karen.Vescovi@churchdwight.com>]
Sent: Thursday, July 12, 2012 12:42 PM
To: CDRH Registration and Listing
Subject: updating Device Listing

Please advise how to update a device listing for K912901--(D064747, Condom) currently it is listing a Lubricated Condom HIS, but need to add Spermicidal Condom product code LTZ to listing, 510(k) covered both. I've tried to update, cancel and re-enter but cannot add this information.

Your assistance is greatly appreciated. You can reach me at the numbers below.

Regards,
Karen

Karen Vescovi
Regulatory Specialist
Church & Dwight Co., Inc.
469 North Harrison Street
Princeton, NJ 08543

(609) 279-7715 phone

(609) 497-7179 fax

karen.vescovi@churchdwight.com

The information contained in this message may be confidential and/or subject to legal privilege, and is for the use of the intended addressee only. Any unauthorized use, dissemination or copying of the information in this message is strictly prohibited. If you have received this message in error, please notify the sender immediately and delete this message.

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JAN 23 1990

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

Stephen C. Kolakowsky
Director, Regulatory Affairs
Carter Products
Division of Carter Wallace Inc.
P.O. Box 1001
Half Acre Road
Cranbury, New Jersey 08512-0181

Re: K895640/B
MAGNUM^R PLUS Latex Condoms with
Spermicidal Silicone Lubricant
Dated: January 8, 1990
Received: January 9, 1990
Regulatory Class: II
21 CFR 884.5310

Dear Mr. Kolakowsky:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Performance Standards) or class III (Premarket Approval) 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 895. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a pre-Amendments device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in anyway represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device please contact the Division of Compliance Operations, Regulatory Guidance Branch (HFZ-323) at (301) 427-8040. Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of OB-GYN, ENT,
and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

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Memorandum

From REVIEWER(S) - NAME(S) Kuchinski (HFZ-470)

Subject 510(k) NOTIFICATION K 895640 B

To THE RECORD

It is my recommendation that the subject 510(k) Notification:

- (A) Is substantially equivalent to marketed devices.
- (B) Requires premarket approval. NOT substantially equivalent to marketed devices.
- (C) Requires more data.
- (D) Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Additional Comments:

The submitter requests under 21 CFR §807.95:

- No Confidentiality
- Confidentiality for 90 days
- Continued Confidentiality exceeding 90 days

Predicate Product Code w/Panel and class:

85 HIS Class II 21 CFR 884.5310

Additional Product Code(s) w/Panel (optional):

REVIEW:

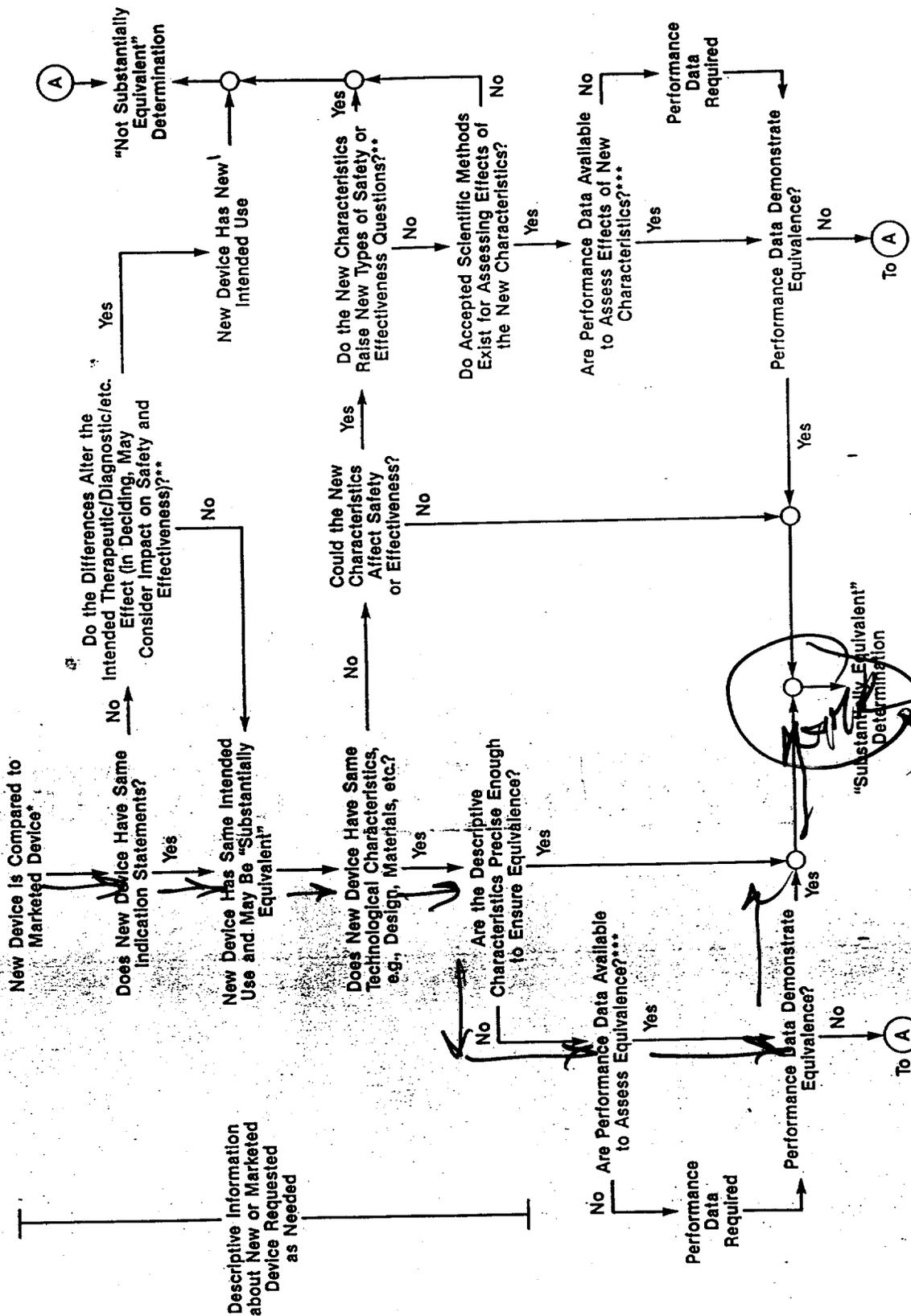
Rajiv G. Kammurthi 1/12/90
(BRANCH CHIEF) (DATE)

FINAL REVIEW:

David A. Segerson 1/22/90
(DIVISION DIRECTOR) (DATE)

7
2

510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



* 510(k) Submissions Compare New Devices to Marketed Devices. FDA Requests Additional Information if the Relationship Between Marketed and "Predicate" (Pre-Amendments or Reclassified Post-Amendments) Devices is Unclear.

** This Decision is Normally Based on Descriptive Information Alone, But Limited Testing Information is Sometimes Required.

*** Data May Be in the 510(k), Other 510(k)s, The Center's Classification Files, or the Literature.

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MEMORANDUM

To: The Record

510(k) Number: K895640/B

From: J. Michael Kuchinski

Applicant: Carter Products

Division of Carter-Wallace, Inc.

P.O. Box 1001

Half Acre Road

Cranbury, New Jersey 08512-0181

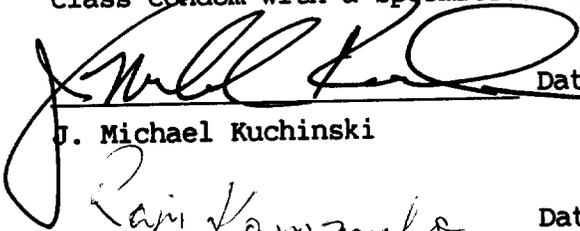
Contact: Stephen C. Kolakowsky

Device Name: MAGNUM^R Plus Latex Condom with Spermicidal Silicone
Lubricant

This submission contains results of accelerated aging testing in support of a 2 (two) year expiration date for the spermicidal component of this combination device. Essentially, the data supports a 2 year expiration, and given our understanding of N-9, 2 years is supportable.

Supplement A identified a proposal for real time testing.

I recommend this application be found substantially equivalent to the generic class condom with a spermicidal lubricant, 21 CFR 884.5310, 85 HIS.


Date: 01/11/90
J. Michael Kuchinski


Date: 1/12/90
Chief Ob-Gyn Branch

concur

do not concur / /

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

JANUARY 11, 1990

CARTER-WALLACE, INC.
ATTN: STEPHEN KOLAKOWSKY
P.O. BOX 1001
HALF ACRE ROAD
CRANBURY, NJ 08512

D.C. Number : K895640
Received : 01-09-90
90th Day : 04-09-90
Product : MAGNUM PLUS LATEX
CONDOM
W/SPERMICIDAL LUBRIC

The additional information you have submitted has been received.

-- We will notify you when the processing of this submission has been completed or if any additional information is required. You are required to wait ninety (90) days after the received date shown above or until receipt of a "substantially equivalent" letter before placing the product into commercial distribution. We intend to complete our review expeditiously and within ninety days. Occasionally, however, a submitter will not receive a final decision or a request for additional information until after ninety days has elapsed. Be aware that FDA is able to continue the review of a submission beyond the ninety day period and might conclude that the device is not substantially equivalent. A "not substantially equivalent" device may not be in commercial distribution without an approved premarket approval application or reclassification of the device. We, therefore, recommend that you not market this device before FDA has made a final decision. Thus, if you have not received a decision within ninety days, it would be prudent to check with FDA to determine the status of your submission.

All correspondence concerning your submission MUST be sent to the Document Mail Center at the above address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification application. Telefax material will not be accepted nor considered as part of your official premarket notification application, unless specifically requested of you by an FDA official.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or their toll-free number (800) 638-2041, or contact me at (301) 427-1190.

Sincerely yours,

Robert I. Chissler
Premarket Notification Coordinator
Office of Device Evaluation
Center for Devices and
Radiological Health

CARTER PRODUCTS

DIVISION OF CARTER-WALLACE, INC

K895640/B

P.O. BOX 1001 • HALF ACRE ROAD • CRANBURY, NEW JERSEY 08512-0181 • 609 655-6000

VIA Federal Express

January 8, 1990

JAN - 9 1990

Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

ATTN: J. Michael Kuchinski

Re: 510(k) Notification #K895640
MAGNUM® PLUS Latex Condoms
With Spermicidal Silicone Lubricant

**THIS SUBMISSION CONTAINS CONFIDENTIAL COMMERCIAL
INFORMATION AS DEFINED IN 21 CFR 20.61 WHICH IS TO BE HELD
CONFIDENTIAL PURSUANT TO 21 CFR 20.61(c) and 807.95**

Gentlemen:

In our telephone conversation on January 5, 1990, Mr. Kuchinski requested additional information in reference to the above captioned 510(k) Notification regarding data supporting the tentative shelf life of two (2) years assigned to the nonoxynol-9 (spermicide) component of the MAGNUM® PLUS condom. The requested data is enclosed.

These data are for four (4) different lots of condoms with spermicidal lubricant. As indicated in our letter of December 14, 1989, a 2-year expiration date has been assigned to the condom and spermicidal lubricant based on the accelerated aging at (b) [redacted] s.

If there are any questions regarding this additional information, please call Ms. Janet Basilotta at (609) 655-6404 or the undersigned at (609) 655-6308.

Sincerely,

Stephen C. Kolakowsky
Stephen C. Kolakowsky
Director
Regulatory Affairs

SCK:pds
ATTACHMENT
B:50A008

In Duplicate

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MAGNUM PLUS
STABILITY TESTING
NONOXYNOL-9

(b)(4)



B: 50A008

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFE-401)
1390 Piccard Drive
Rockville, Maryland 20850

JANUARY 9, 1990

CARTER-WALLACE, INC.
ATTN: STEPHEN KOLAKOWSKY
P.O. BOX 1001
HALF ACRE ROAD
CRANBURY, NJ 08512

D.C. Number: K895640
Product : MAGNUM PLUS LATEX
CONDOM
W/SPERMICIDAL LUBRIC

-- We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. This information and all correspondence concerning your submission MUST be sent to the Document Mail Center at the above address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification application. Telefax material will not be accepted nor considered as part of your official premarket notification application, unless specifically requested of you by an FDA official.

When your additional information is received by the Office of Device Evaluation Document Mail Center (address above), the 90-day period will begin again.

If after 30 days the requested information is not received, we will stop reviewing your submission and proceed to withdraw your file from our review system. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and the 90-day time period will begin again.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or their toll-free number (800) 638-2041, or contact me at (301) 427-1190.

Sincerely yours,

Robert I. Chissler
Premarket Notification Coordinator
Office of Device Evaluation
Center for Devices and
Radiological Health

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DO NOT REMOVE THIS ROUTE SLIP!!!!

K-89-5640

1/9/90

FROM: CARTER-WALLACE, INC. ATTN: STEPHEN KOLAKOWSKY P.O. BOX 1001 HALF ACRE ROAD CRANBURY, NJ 08512		LETTER DATE 09/18/89	LOGIN DATE 09/19/89	DUE DATE 03/15/90
		TYPE OF DOCUMENT: 510 (k)		CONTROL # K895640
SHORT NAME: CARTWALL		ESTABLISHMENT NO: 2210299		
TO: ODE/DMC	CONT. CONF.: ? STATUS : H REV PANEL : OB PAN/PROD CODE(S): OB / / /			
SUBJECT: MAGNUM PLUS LATEX CONDOM W/SPERMICIDAL LUBRICANT				
DECISION: DECISION DATE: / /	RQST INFO DATE: 12/11/89 DATE: 01/09/90 DATE: / / DATE: / / DATE: / / DATE: / /	INFO DUE DATE: 01/10/90 DATE: 02/08/90 DATE: / / DATE: / / DATE: / / DATE: / /		

SUPPLEMENT: 01

LTR DATE: 891214

LOGIN DATE: 891215

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9



Memorandum

Date _____
 From REVIEWER(S) - NAME(S) Kuchinski (#FZ-470)
 Subject 510(k) NOTIFICATION K895640 / A
 To THE RECORD

It is my recommendation that the subject 510(k) Notification:

- (A) Is substantially equivalent to marketed devices.
- (B) Requires premarket approval. NOT substantially equivalent to marketed devices.
- (C) Requires more data.
- (D) Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Additional Comments:

Identified per telecon w/ S. Kolakowsky (1/5/90) that the actual data supporting shelf-life is necessary for S.E. of the shelf-life of N-9. Mr. Kolakowsky stated that he would supply either the data for this product or reference a prior submission that contained the type of information necessary. I recommend placing the document on hold. JMK 1/5/90

The submitter requests under 21 CFR §807.95:

- No Confidentiality
- Confidentiality for 90 days
- Continued Confidentiality exceeding 90 days

Predicate Product Code w/Panel and class:

85

Additional Product Code(s) w/Panel (optional):

REVIEW:

Rajiv G. Kamnula 1/5/90
 (BRANCH CHIEF) (DATE)

FINAL REVIEW:

 (DIVISION DIRECTOR) (DATE)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

**Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFE-401)
1390 Piccard Drive
Rockville, Maryland 20850**

DECEMBER 18, 1989

CARTER-WALLACE, INC.
ATTN: STEPHEN KOLAKOWSKY
P.O. BOX 1001
HALF ACRE ROAD
CRANBURY, NJ 08512

D.C. Number : K895640
Received : 12-15-89
90th Day : 03-15-90
Product : MAGNUM PLUS LATEX
CONDOM
W/SPERMICIDAL LUBRIC

The additional information you have submitted has been received.

-- We will notify you when the processing of this submission has been completed or if any additional information is required. You are required to wait ninety (90) days after the received date shown above or until receipt of a "substantially equivalent" letter before placing the product into commercial distribution. We intend to complete our review expeditiously and within ninety days. Occasionally, however, a submitter will not receive a final decision or a request for additional information until after ninety days has elapsed. Be aware that FDA is able to continue the review of a submission beyond the ninety day period and might conclude that the device is not substantially equivalent. A "not substantially equivalent" device may not be in commercial distribution without an approved premarket approval application or reclassification of the device. We, therefore, recommend that you not market this device before FDA has made a final decision. Thus, if you have not received a decision within ninety days, it would be prudent to check with FDA to determine the status of your submission.

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If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or their toll-free number (800) 638-2041, or contact me at (301) 427-1190.

Sincerely yours,

Robert I. Chissler
Premarket Notification Coordinator
Office of Device Evaluation
Center for Devices and
Radiological Health

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CARTER PRODUCTS

DIVISION OF CARTER-WALLACE, INC.

P.O. BOX 1001 • HALF ACRE ROAD • CRANBURY, NEW JERSEY 08512-0181 • 609-655-6000

K895640/A

VIA Federal Express

December 14, 1989

Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850
ATTN: J. Michael Kuchinski

Re: 510(k) Notification #K895640
MAGNUM® PLUS Latex Condoms
With Spermicidal Silicone Lubricant

**THIS SUBMISSION CONTAINS CONFIDENTIAL COMMERCIAL
INFORMATION AS DEFINED IN 21 CFR 20.61 WHICH IS TO BE HELD
CONFIDENTIAL PURSUANT TO 21 CFR 20.61(c) and 807.95**

Gentlemen:

This is in response to the telephone conversation with Mr. Kuchinski on December 7, 1989, regarding the above captioned 510(k) Notification. Additional information was requested, namely, support for the claimed expiration date of two (2) years for the spermicidal lubricant of the subject condom as noted on page 12 of the 510(k).

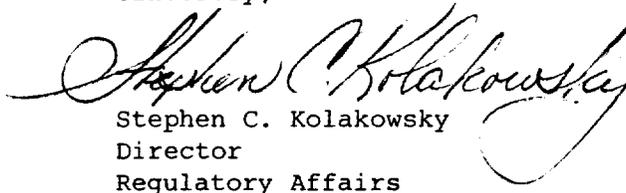
First, please be advised that Carter has decided not to use a (b) concentration label claim for the spermicidal ingredient, nonoxynol-9, as described on pages 3 and 9 of the 510(k), but rather 5.5% in line with the present label claim for its other TROJAN® brand condoms with spermicidal lubricant. All other parameters, i.e, fill volume and formulation of the lubricant, will remain the same.

- 2 -

To support the claimed expiration date of 2 years (24 months) from the date of manufacture, Carter has established stability studies. As explained on page 8 of the 510(k), the spermicidally lubricated condoms were exposed to accelerated aging conditions of 70°C for 7 days in accordance with ASTM Standard D3492 with the results as presented on pages 11 and 12 of the 510(k). In addition, spermicidally lubricated condoms have been placed at room temperature, 40°C, 50°C, and 37°C/75% relative humidity storage. The physical characteristics of the condoms are measured at periods of 1, 3, and 6 months at all storage temperatures; at 12 months at room temperature 40°C and 37°C/75% RH; and at 24, 36, 48, and 60 months at room temperature. The nonoxynol-9 spermicidal component of the lubricant is assayed at periods of 1 and 3 months at room temperature, 40°C and 50°C; at 6 months at room temperature and 40°C; and at 12, 24, 36, 48, and 60 months at room temperature. Based on the accelerated aging at 50°C for 3 months, a 2-year expiration has been assigned to the condom and the lubricant. Additional pilot batch material has been placed on stability study, and production lot material will be selected for stability monitoring by the Quality Control Department on a routine basis when the product begins production for market.

We believe the above information fulfills the request for additional information. If there are any additional questions, please call Ms. Janet Basilotta at (609) 655-6404 or the undersigned at (609) 655-6308.

Sincerely,


Stephen C. Kolakowsky
Director
Regulatory Affairs

SCK:pds
B:59A346

In Duplicate

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14

CARTER PRODUCTS

DIVISION OF CARTER-WALLACE, INC.

P.O. BOX 1001 • HALF ACRE ROAD • CRANBURY, NEW JERSEY 08512-0181 • 609-655-6000

VIA Federal Express

December 14, 1989

Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850
ATTN: J. Michael Kuchinski

RECEIVED
DEC 15 11:49 AM '89

Re: 510(k) Notification #K895640
MAGNUM® PLUS Latex Condoms
With Spermicidal Silicone Lubricant

**THIS SUBMISSION CONTAINS CONFIDENTIAL COMMERCIAL
INFORMATION AS DEFINED IN 21 CFR 20.61 WHICH IS TO BE HELD
CONFIDENTIAL PURSUANT TO 21 CFR 20.61(c) and 807.95**

Gentlemen:

This is in response to the telephone conversation with Mr. Kuchinski on December 7, 1989, regarding the above captioned 510(k) Notification. Additional information was requested, namely, support for the claimed expiration date of two (2) years for the spermicidal lubricant of the subject condom as noted on page 12 of the 510(k).

First, please be advised that Carter has decided not to use a (b)(4) concentration label claim for the spermicidal ingredient, nonoxynol-9, as described on pages 3 and 9 of the 510(k), but rather 5.5% in line with the present label claim for its other TROJAN® brand condoms with spermicidal lubricant. All other parameters, i.e, fill volume and formulation of the lubricant, will remain the same.

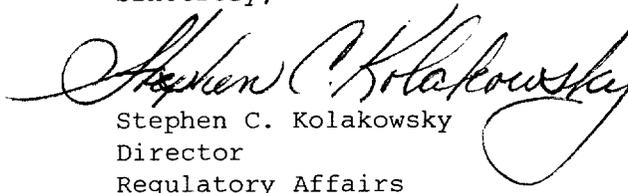
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- 2 -

To support the claimed expiration date of 2 years (24 months) from the date of manufacture, Carter has established stability studies. As explained on page 8 of the 510(k), the spermicidally lubricated condoms were exposed to accelerated aging conditions of 70°C for 7 days in accordance with ASTM Standard D3492 with the results as presented on pages 11 and 12 of the 510(k). In addition, spermicidally lubricated condoms have been placed at room temperature, 40°C, 50°C, and 37°C/75% relative humidity storage. The physical characteristics of the condoms are measured at periods of 1, 3, and 6 months at all storage temperatures; at 12 months at room temperature 40°C and 37°C/75% RH; and at 24, 36, 48, and 60 months at room temperature. The nonoxynol-9 spermicidal component of the lubricant is assayed at periods of 1 and 3 months at room temperature, 40°C and 50°C; at 6 months at room temperature and 40°C; and at 12, 24, 36, 48, and 60 months at room temperature. Based on the accelerated aging at 50°C for 3 months, a 2-year expiration has been assigned to the condom and the lubricant. Additional pilot batch material has been placed on stability study, and production lot material will be selected for stability monitoring by the Quality Control Department on a routine basis when the product begins production for market.

We believe the above information fulfills the request for additional information. If there are any additional questions, please call Ms. Janet Basilotta at (609) 655-6404 or the undersigned at (609) 655-6308.

Sincerely,


Stephen C. Kolakowsky
Director
Regulatory Affairs

SCK:pds
B:59A346

In Duplicate



DEC 11 1989

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

Mr. Stephen C. Kolakowsky
Director, Regulatory Affairs
Carter Products
Division of Carter Wallace, Inc.
P.O. Box 1001
Half Acre Road
Cranbury, New Jersey 08512 - 0181

Re: K895640
Magnum^R PLUS Latex Condoms with
Spermicidal Silicone Lubricant
Dated: September 18, 1989
Received: September 19, 1989

Dear Mr. Kolakowsky:

We have reviewed your Section 510(k) notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a device marketed prior to May 28, 1976, the enactment date of the Medical Device Amendments, based solely on the information you provided. In order for us to complete the review of your submission, we require data to support the expiration date of the drug component of the Magnum^R PLUS Latex Condom with Spermicidal Silicone Lubricant. The data supporting the expiration date of the drug component should quantitatively assess the amount of spermicide available over time and the effect of this component on the latex membrane.

We believe that this information is necessary for us to determine whether or not this device is substantially equivalent to a pre-Amendments device with regard to its safety and effectiveness.

You may not market this device until 90 days after you have provided adequate information described above and required by 21 CFR 807.87(f) and (h). If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemptions (IDE) regulations.

The requested information should reference your above 510(k) number and should be submitted to:

Food and Drug Administration
Center for Devices and
Radiological Health
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

Page 2 - Mr. Stephen C. Kolakowsky

If the requested information is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days, it will be considered and processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete.

If you have any questions concerning the contents of this letter, please contact Raju G. Kammula, D.V.M., Ph.D., at (301) 427-1180. If you have general questions regarding 510(k) procedures or policies, you may contact Mr. Robert I. Chissler at (301) 427-1190. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

for David A. Segerson
Lillian Yin, Ph.D.
Director, Division of OB-GYN,
ENT and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

DO NOT REMOVE THIS ROUTE SLIP!!!!

K-89-5640

12/11/89

FROM: CARTER-WALLACE, INC. ATTN: STEPHEN KOLAKOWSKY P.O. BOX 1001 HALF ACRE ROAD CRANBURY, NJ 08512		LETTER DATE 09/18/89	LOGIN DATE 09/19/89	DUE DATE 12/18/89
		TYPE OF DOCUMENT: 510 (k)		CONTROL # K895640
SHORT NAME: CARTWALL		ESTABLISHMENT NO: 2210299		
TO: ODE/DMC		CONT. CONF.: ? STATUS : H REV PANEL : OB PAN/PROD CODE(S): OB/ / /		
SUBJECT: MAGNUM PLUS LATEX CONDOM W/SPERMICIDAL LUBRICANT				
DECISION: DECISION DATE: / /		RQST INFO DATE: 12/11/89 DATE: / / DATE: / / DATE: / / DATE: / / DATE: / /		INFO DUE DATE: 01/10/90 DATE: / / DATE: / / DATE: / / DATE: / / DATE: / /

DEPARTMENT OF HEALTH AND HUMAN SERVICES

DEC 11

Mr. Stephen C. Kolakowsky
 Director, Regulatory Affairs
 Carter Products
 Division of Carter Wallace, Inc.
 P.O. Box 1001
 Half Acre Road
 Cranbury, New Jersey 08512 - 0181

Re: K895640
 Magnum^R PLUS Latex Condoms with
 Spermicidal Silicone Lubricant
 Dated: September 18, 1989
 Received: September 19, 1989

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The requested information should reference your above 510(k) number and should be submitted to:

Food and Drug Administration
 Center for Devices and
 Radiological Health
 Document Mail Center (HFZ-401)

FILE
 COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
2A70	Ruch...	12/18/89			
2A70	Kammala	12/18/89			
2A70	Seg...	12/18/89			

Questions? Contact FDA/CDRH/OCE/DID at CDRH.FOIA@FDA.HHS.gov or 301-796-8118

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U.S. GPO 1986-161-865

20

Page 2 - Mr. Stephen C. Kolakowsky

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Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of OB-GYN,
ENT and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

jmk 8.72
Draft:12/05/89:JMKuchinski
Final:12/07/89:slj



Memorandum

ate .

From REVIEWER(S) - NAME(S) Kucitinski (HFZ-470)

Subject 510(k) NOTIFICATION K-895640

To THE RECORD

It is my recommendation that the subject 510(k) Notification:

- (A) Is substantially equivalent to marketed devices.
- (B) Requires premarket approval. NOT substantially equivalent to marketed devices.
- (C) Requires more data.
- (D) Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Additional Comments:

The submitter requests under 21 CFR §807.95:

- No Confidentiality
- Confidentiality for 90 days
- Continued Confidentiality exceeding 90 days

Predicate Product Code w/Panel and class:

85

Additional Product Code(s) w/Panel (optional):

REVIEW: Reju G. Kammula 12/7/89 (DATE)

(BRANCH CHIEF)

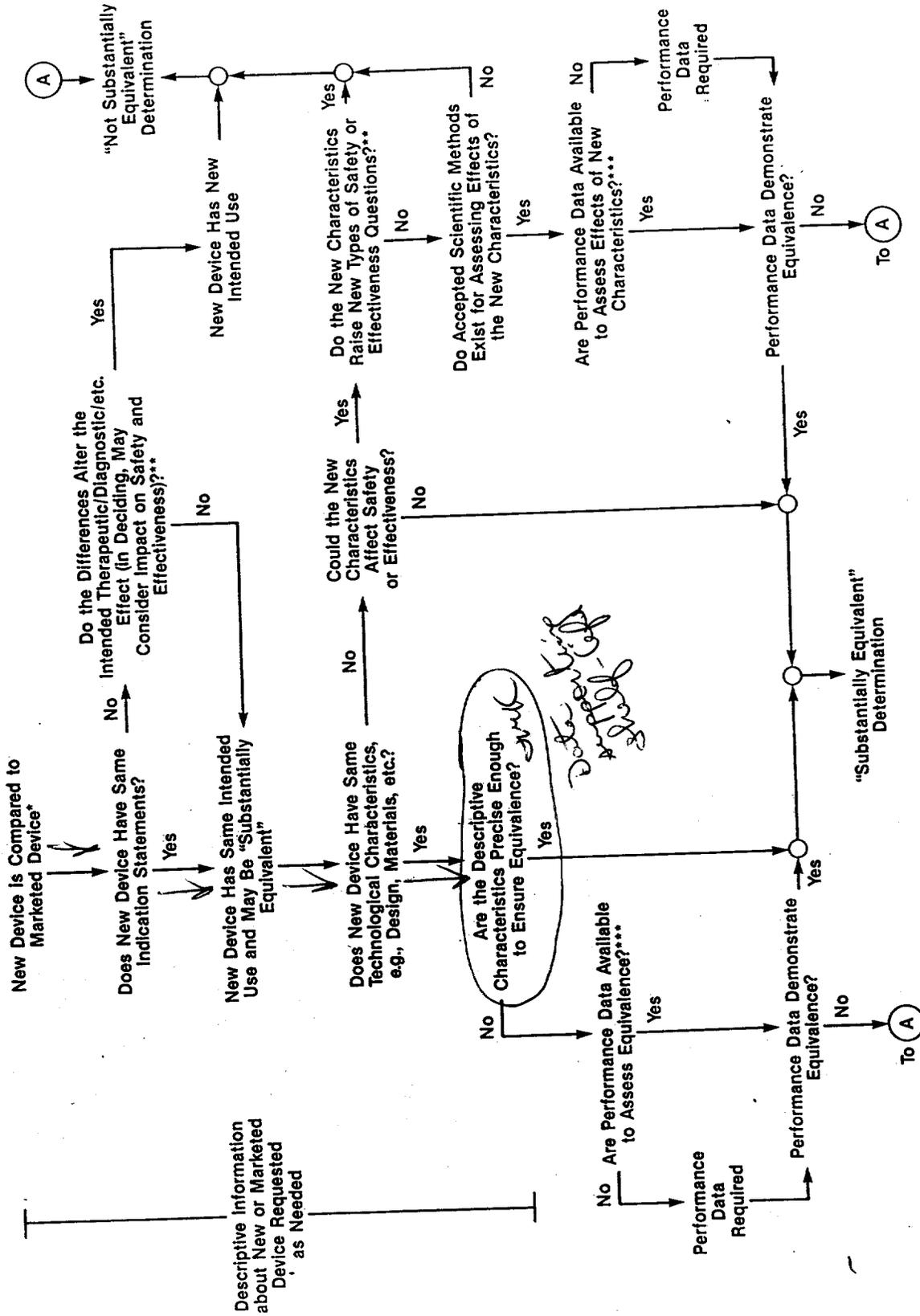
FINAL REVIEW: David A. Segerson 12/8/89 (DATE)

(DIVISION DIRECTOR)

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7
23

510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



** This Decision is Normally Based on Descriptive Information Alone, But Limited Testing Information is Sometimes Required. ... Data May Be in the 510(k), Other 510(k)s, The Center's Classification Files, or the Literature.

* 510(k) Submissions Compare New Devices to Marketed Devices. FDA Requests Additional Information if the Relationship Between Marketed and "Predicate" (Pre-Amendments or Reclassified Post-Amendments) Devices is Unclear.

24 BEST COPY AVAILABLE

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING DOCUMENTATION
(to be used in conjunction with flow-chart and record memorandum)

From: Reviewer(s) Name(s): J. Michael Kuchinski

Division and Branch: Division of Ob-Gyn, ENT, and Dental Devices

To: 510(k) File Number: K895640

Applicant (Name and Address): Carter Products
Box 1001
Half Acre Road
Cranbury, New Jersey 08512-0181

Representative/Consultant (Name and Address): Stephen C. Kowakowsky
Director, Regulatory Affairs

Product Name: a. Trade/Proprietary:

Magum^R Plus Latex Condom with Spermicidal Silicone Lubricant

b. Generic/Common: Condom; 21 CFR 884.5310

Is product a device?:

YES

NO -- EXPLAIN (e.g. Drug, Biological etc.)

STOP REVIEW IF ANSWER IS NO

Is device subject to 510(k)?:

YES

NO -- EXPLAIN (e.g. Exempt by regulation, general purpose article, etc.)

EXEMPT - Regulation Number:

STOP REVIEW IF ANSWER IS NO

REVIEW DOCUMENTATION AND DECISION LOGIC

PART I. DEVICE DESCRIPTION

Provide a summary about the important features or uses of the device. The following should be considered when preparing the summary. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Provide a summary about the devices design, materials, physical properties and toxicology profile if important. Is the device sterile? Is the device for single use? Is the device for home use or prescription use? Does the device contain drug or biological product as a component? Is this device a kit?

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SUMMARY

REQUIRED INFORMATION for a CONDOM 510(k)

1. Identify the manufacturer and developer of the product specifications.

ANS: Carter Wallace, Inc. is the product specifications developer. The actual latex condom is manufactured by Fuji Latex Company, Ltd., 19-1, 3-CHROME, Kanbanishiki-CHO, CHIYODA-KU, Tokyo, JAPAN and distributed through Circle Rubber, Newark, New Jersey.

2. Provide the chemical composition of the dusting agent and the lubricant to be applied to the condoms;

ANS: Dusting Agent; [REDACTED] (b)(4)

Lubricant; (b)(4) [REDACTED]

3. Provide the chemical composition of the color additive used with the condoms, identifying the color index number and a reference to the specific color additive listing (21 CFR reference). If the color additive cannot be identified as having applicability as an additive in a food, drug, cosmetic or medical device, provide biocompatibility data to support its safe use;

ANS: No color is added to the latex.

4. Provide a description of the product specifications for width, length, thickness and the physical requirement specifications.

ANS: This device is identified as ASTM Type II, Style 2, Class A, that is textured, reservoir end and within the ASTM width range of 52 +/- 2 mm. This meets the minimum requirements for dimensions and physical requirements for the ASTM D-3492 for condom specifications.

5. Provide a detailed description of the test procedures used by the manufacturer to establish the quality of each condom lot or batch, and identify when quality control tests, including any in-process tests, are conducted during the manufacturing process.

ANS: Specific in-process testing is conducted by the manufacturer on the product prior to 100% electronic testing, i.e., dimensions, physical parameters and water leakage testing. Upon receipt of the bulk condoms from Circle Rubber ASTM D-3492 testing performed at (b)(4). Final release testing is conducted by (b)(4) consisting of dimensions, physical parameters and water leakage per ASTM Standard for AQL and inspection levels with sampling plan per MIL 105D, Level II.

6. Provide a detailed description of the electronic testing procedures including a description of the electronic testing machine, the machines' specifications, and operators manual, and a description of the electronic

testing machines' calibration procedures;

ANS: Carter Products has not identified the electronic testing procedure. Nevertheless, this information can be considered unnecessary because of the bulk nature of the product and that Level II sampling is performed both before and after primary packaging occurs.

7. Provide a description of the relationship between the electronic testing machines' calibration procedures (item above) to the physical testing procedures used for product release;

ANS: The manufacturer has not identified any specific relationship between Elec. testing and final release testing.

8. Identify the acceptable quality level (AQL) for dimensions, physical requirements, color fastness and water leakage, define its meaning, and describe the sampling procedure and the inspection level used to achieve the desired AQL.

ANS: The manufacturer has provided the appropriate AQLs for the product according to the ASTM Standard for dimensions, physical parameters and water leakage.

9. Provide copies of labels, labeling and advertisements sufficient to describe the intended use and directions for use; and

ANS: The submission contains draft labeling sufficient to describe the device and has provided adequate directions for use. This labeling also contains the appropriate labeling statement and expiration date statement for the drug component.

10. Identify the chemical composition of the lubricant/spermicide of the condom containing a spermicidal lubricant, provide the volume of lubricant/spermicide delivered to each condom, identify the concentration of the active ingredient and provide data to support the expiration date of the drug component. The data supporting the expiration date of the drug component should quantitatively assess the amount of spermicide available over time and the effect of this component on the latex membrane over time.

ANS: The composition of the lubricant is identified above. The concentration is identified as (b)(4)

██████████ The company has identified a 2 year expiration date for the drug component based on ASTM accelerated testing 70°C for 7 days. The company has identified the Planned Parenthood Federations Agreed Test for Total Spermicidal Power as an acceptance test for the Spermicide and this test should also be used for shelf life verification.

10. Provide data to support the proposed shelf life.

ANS: Company has based shelf life on ASTM accelerated testing and has not identified the appropriate real time studies.

PART II. INTENDED USE:

1. Identify marketed device(s) submitted by the applicant to which the new device is compared, (show 510(k) number and/or device name):

The manufacturer has identified a specific device as predicate, their own Magum^R Condom and the ansell Nuda Plus. The generic class CONDOM with Spermicidal Lubricant, 21 CFR 884.5310 is also identified.

a. Manufactured by: Carter Wallace and/or Ansell.

b. Is the device to which compared the most appropriate?

YES

No — What device is more appropriate and will be used in this review? — Name

—510(k) Number:

c. Comparable device indication statement:

Intended for contraception and reduce risk of STD with appropriate directions for use. Also see FDA guidance letter dated April 7, 1987 and the required limited contraceptive effectiveness statement and expiration date for drug component of the lubricant.

2. New device indication statement:

Intended for contraception and reduce risk of STD with appropriate directions for use. Also see FDA guidance letter dated April 7, 1987 and the required limited contraceptive effectiveness statement and expiration date for drug component of the lubricant.

a. Indication statement same as marketed device:

YES —

- Any variation in warnings or precautions

Yes — Go to II.2.c.

NO — Intended use SE go to Part III

No — Go to II.2.b.

b. Do differences in intended therapeutic, diagnostic, prosthetic, surgical, etc use alter the intended effect?

YES — Identify new use

STOP REVIEW IF ANSWER IS YES - DEVICE NE

No — Go to II.2.c: Don't Know

c. Do any differences in warnings, precautions, etc. raise new issues

of safety and effectiveness?

Yes, - Identify new issue(s):

STOP REVIEW IF ANSWER IS YES - DEVICE NE

No -- Intended use SE go to Part III: Don't Know

PART III. TECHNOLOGICAL CHARACTERISTICS

1. Identify marketed device(s) submitted by applicant to which new device is compared (show 510(k) number and/or device name):

See Part I question 1 regarding the indication statement, also 21 CFR 884.5310 and ASTM Standard for reference.

a. Manufactured by: See above under Part II, question 1.

b. Is the device to which compared the most appropriate?

YES

~~No~~ - What device is more appropriate and will be used in this review: - Name

-510(k) Number

c. Does comparable device conform to any standards?

YES

- Identify standards

ASTM D-3492

No -

2. Device technological characteristics

a. Identify technological characteristics of comparable device:

Reference ASTM Standard D-3492. See under Part I, Summary.

b. Identify technological characteristics of new device:

See Part I, Summary.

c. Compare and discuss difference (between a and b):

There are no differences between the devices.

d. Do the comparable device and the new device have the same technological characteristics?

YES

- go to III.6

No -- go to III.3

3. Differences in technological characteristics:

Do not affect S&E -- go to III.6

Do affect S&E -- go to III.4

Could Affect S&E-- go to III.4

4. Do the new characteristics raise new types of safety or effectiveness questions?

Yes

- Identify new types of questions

STOP REVIEW IF ANSWER IS YES - DEVICE NE

No -- go to III.5

5. Do accepted scientific methods exist for assessing effects of new characteristics?

Yes -- go to III.7

No -

- Explain

STOP REVIEW IF ANSWER IS NO - DEVICE NE

6. Are descriptive characteristics of new device precise enough to ensure equivalence if the new device is manufactured to meet specifications:

Yes

STOP REVIEW IF ANSWER IS YES - DEVICE SE (DO NOT REQUEST PERFORMANCE DATA)

NO -- go to III.7

- Explain

shelf life JK

7. Are adequate performance data available to assess equivalence?

Yes

NO --

- Identify required performance data: See recommendations above within the Part I, Summary. The information necessary is data to support an expiration date.

- REQUEST DATA AND RETURN SUBMISSION TO DOCUMENT CENTER TO BE PLACED ON HOLD.

8. Does performance data demonstrate equivalence?

Yes

- Explain

STOP REVIEW IF ANSWER IS YES - DEVICES SE

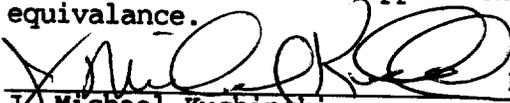
No

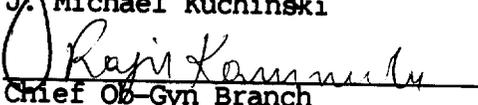
- Explain

STOP REVIEW IF ANSWER IS NO - DEVICE NE

RECOMMENDATION:

I recommend that the applicant be requested to provide additional information, data to support the expiration date, to determine substantial equivalence.

 Date: 11/22/89
J. Michael Kuchinski

 Date: 12/7/89
Chief Ob-Gyn Branch

Concur / ✓

Do not concur / /

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

SEPTEMBER 20, 1989

CARTER-WALLACE, INC.
ATTN: STEPHEN KOLAKOWSKY
P.O. BOX 1001
HALF ACRE ROAD
CRANBURY, NJ 08512

D.C. Number : K895640
Received : 09-19-89
90th Day : 12-18-89
Product : MAGNUM PLUS LATEX
CONDOM
W/SPERMICIDAL LUBRIC

-- The Premarket Notification you have submitted as required under Section 510(k) of the Federal Food, Drug, and Cosmetic Act for the above referenced device has been received and assigned an unique document control number (D.C. Number above). Please cite this D.C. Number in any future correspondence that relates to this submission.

We will notify you when the processing of this submission has been completed or if any additional information is required. You are required to wait ninety (90) days after the received date shown above or until receipt of a "substantially equivalent" letter before placing the product into commercial distribution. We intend to complete our review expeditiously and within ninety days. Occasionally, however, a submitter will not receive a final decision or a request for additional information until after ninety days has elapsed. Be aware that FDA is able to continue the review of a submission beyond the ninety day period and might conclude that the device is not substantially equivalent. A "not substantially equivalent" device may not be in commercial distribution without an approved premarket approval application or reclassification of the device. We, therefore, recommend that you not market this device before FDA has made a final decision. Thus, if you have not received a decision within ninety days, it would be prudent to check with FDA to determine the status of your submission.

All correspondence concerning your submission MUST be sent to the Document Mail Center at the above address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification application. Telefax material will not be accepted nor considered as part of your official premarket notification application, unless specifically requested of you by an FDA official.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or their toll-free number (800) 638-2041, or contact me at (301) 427-1190.

Sincerely yours,

Robert I. Chissler
Premarket Notification Coordinator
Office of Device Evaluation
Center for Devices and
Radiological Health

K-895640

CARTER PRODUCTS

DIVISION OF CARTER-WALLACE, INC.

P.O. BOX 1001 • HALF ACRE ROAD • CRANBURY, NEW JERSEY 08512-0181 • 609-655-6000

September 18, 1989

Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

Re: 510(k) Notification
MAGNUM® PLUS Latex Condoms
With Spermicidal Silicone Lubricant

**THIS SUBMISSION CONTAINS CONFIDENTIAL COMMERCIAL
INFORMATION AS DEFINED IN 21 CFR 20.61 WHICH IS TO BE HELD
CONFIDENTIAL PURSUANT TO 21 CFR 20.61(c) AND 807.95**

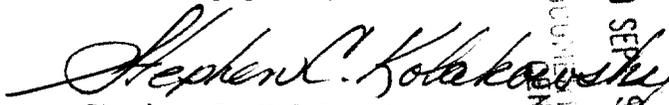
Gentlemen:

The enclosed Premarket Notification Submission is submitted under section 510(k) of the Federal Food, Drug, and Cosmetic Act. Two copies of this premarket notification are being submitted for Carter Products Division of Carter-Wallace, Inc., pursuant to Subpart E of 21 CFR Part 807.

The purpose of this 510(k) submission is to notify FDA that Carter Products intends to introduce a MAGNUM® PLUS Latex Condom with Spermicidal Silicone Lubricant.

We look forward to your concurrence with our finding of substantial equivalence for this device. Should you have any questions concerning this notification, please telephone Janet Basilotta at (609) 655-6404.

Sincerely yours,



Stephen C. Kolakowsky
Director
Regulatory Affairs

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1989 SEP 19 PM 12:18
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SCK:pds
Enclosure

CARTER PRODUCTS

DIVISION OF CARTER WALLACE, INC.

P.O. BOX 1001 • HALF ACRE ROAD • CRANBURY, NEW JERSEY 08512 0181 • 609 655 6000

September 18, 1989

Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

Re: 510(k) Notification
MAGNUM® PLUS Latex Condoms
With Spermicidal Silicone Lubricant

**THIS SUBMISSION CONTAINS CONFIDENTIAL COMMERCIAL
INFORMATION AS DEFINED IN 21 CFR 20.61 WHICH IS TO BE HELD
CONFIDENTIAL PURSUANT TO 21 CFR 20.61(c) AND 807.95**

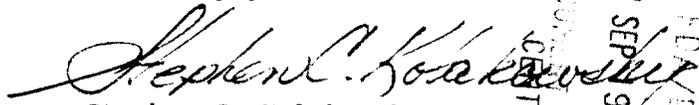
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Sincerely yours,



Stephen C. Kolakowsky
Director
Regulatory Affairs

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1989 SEP 9 PM 12:18
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SCK:pds
Enclosure

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510(k): MAGNUM® PLUS

CONTENTS

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Certification of Confidentiality.....iii
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Establishment Registration Number.....1
Device Classification Under Section 513.....1
Action Taken to Comply with Section 514.....1
Proposed Labels, Labeling and Advertising
 Unit Container Label.....2
 Carton Label.....3
Substantial Equivalence Statement.....6
Additional Information Regarding the Device.....14
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510(k): MAGNUM® PLUS

CERTIFICATION OF CONFIDENTIALITY

Pursuant to FDA Regulation [21 CFR 807.95(b)] we request that the Food and Drug Administration hold as confidential commercial information our intent to market the device described in this notification.

We hereby certify (i) that our intent to market the device is confidential information; (ii) that neither Carter-Wallace, Inc., nor, to the best of its knowledge, anyone else has disclosed through advertising or any other manner, our intent to market the device except as provided under 21 CFR 807.95(b); (iii) that Carter-Wallace, Inc. will immediately notify the FDA if our intent to market the device is disclosed by Carter Wallace, Inc., to anyone, except as provided by 21 CFR 807.95(b); (iv) that Carter-Wallace, Inc., has taken precautions to protect the confidentiality of our intent to market the device; and (v) that Carter-Wallace, Inc., understands that the submission to the government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q).

510(k): MAGNUM® PLUS

DEVICE NAME

PROPRIETARY NAME:

MAGNUM® PLUS Latex Condom
With Spermicidal Lubricant

COMMON NAME:

Latex Condom with spermicidal lubricant

CLASSIFICATION NAME:

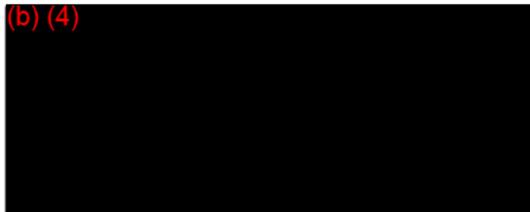
Condom with spermicidal lubricant

ESTABLISHMENT REGISTRATION

#2210299

Carter Wallace, Inc
Carter Products Division
P.O. Box 1001, Half Acre Road
Cranbury, New Jersey 08512-0181

(b) (4)

A large black rectangular redaction box covers the right side of the page, obscuring information related to the establishment registration.

DEVICE CLASSIFICATION

Condoms with spermicidal lubricant have been classified as Class II medical devices. [21 CFR 884.5310]

ACTION TAKEN TO COMPLY WITH SECTION 514

The Commissioner has not to date issued any regulation promulgated in accordance with Section 514 of the FFD&C Act which would establish a performance standard for products of this product type. Therefore, no action has been taken to comply with any such performance standard.

The American Society for Testing and Materials (ASTM) has established voluntary industry Standard Specifications for Rubber Contraceptives (Condoms) designated D3492-83. Carter-Wallace, Inc. follows this voluntary standard as a guideline for testing its latex condom products where applicable.

510(k): MAGNUM® PLUS

Proposed Labels, Labeling and Advertising*

CONDOM PACKET LABEL

FRONT

MAGNUM® PLUS
BRAND CONDOM
with Spermicidal Lubricant

BEFORE USING, READ DIRECTIONS
AND WARNING ON CARTON

ONE LUBRICATED LATEX CONDOM
Distributed by CARTER PRODUCTS
Division of Carter-Wallace, Inc.
New York, N.Y. 10153

TEAR HERE

BACK

MAGNUM® PLUS
BRAND CONDOM
with Spermicidal Lubricant

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 you lose your erection before withdrawal and some semen spills 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.

TEAR HERE

*NOTE: Advertising specific for this MAGNUM® PLUS Brand Condom Product has not been developed.

prominence of labeling statement. OK JMK

B:A9248B

02

510(k): MAGNUM® PLUS

CONDOM CARTON LABEL

FRONT

MAGNUM® PLUS

Brand Latex Condom
with Spermicidal Lubricant

Highly effective against pregnancy and helps reduce the risk of spreading many sexually transmitted diseases.

TO OPEN: PULL BACK. TEAR OFF. Carefully follow instructions for use on inside of carton.

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 you lose your erection before withdrawal and some semen spills 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.

3/12 LUBRICATED LATEX CONDOMS

BOTTOM

DISTRIBUTED BY CARTER PRODUCTS
DIVISION OF CARTER-WALLACE, INC.
NEW YORK, N.Y. 10153

Manufactured for Carter Products in Japan,
specially tested and packaged in USA
©1989 CARTER-WALLACE, INC.

(UPC)

PRINTED IN USA.

SIDE

The expiration date below applies only to the spermicidal lubricant, not the condom. MMDDYY

B:A9248B

510(k): MAGNUM® PLUS
Condom Carton Label (continued)

BACK

MAGNUM® PLUS

Brand Latex Condom
with Spermicidal Lubricant

Active Ingredient: Nonoxynol-9 (6.5%)
Store in a dry place at room temperature, 59°-86°F (15°-30°C).

MAGNUM® Brand Latex Condoms, when properly used, are highly effective against pregnancy - although no contraceptive can guarantee 100% effectiveness. Any use of **MAGNUM®** Brand Latex Condoms for other than vaginal intercourse can increase the potential of damage to the condom. **MAGNUM®** Brand Latex Condoms, when properly used, may help reduce the risk of catching or spreading many Sexually Transmitted Diseases ("STD") such as syphilis, gonorrhea, chlamydia infections, genital herpes and AIDS; however, they cannot eliminate the risk. For maximum benefits, it is important to follow the directions for use printed on the inside of this package. Failure to do so may result in the loss of the benefits of a condom. During intimate contact, lesions and various body fluids can transmit STDs. Therefore, the condom should be applied each and every time before any such contact occurs.

FOR COMPLETE INSTRUCTIONS FOR USE OF A CONDOM SEE INSIDE OF CARTON.

B:A9248B

04

510(k) : MAGNUM® PLUS

INSIDE CARTON

**IMPORTANT
INSTRUCTIONS FOR USE OF A CONDOM**

1. Place a new condom on the penis each time, prior to any foreplay, genital contact or penetration to avoid contact with any body fluid that may contain STD organisms.
2. Pull the condom over the head of the erect penis. Squeeze end slightly to release air to avoid an air pocket.
3. Slowly unroll all the way to the base of the penis. If the condom does not unroll to the base of the penis, it has been put on incorrectly and should be discarded.
4. If a lubricant is desired, use water-based lubricant. Do not use oil-based lubricants, such as those made with petroleum jelly, mineral oil, vegetable oil, or cold cream, as they may damage the condom.
5. After climax, ejaculation or "coming", the penis should be withdrawn slowly from the vagina. The top of the condom (RIM) should be held firmly when withdrawing to avoid spilling the semen. The withdrawal should be done as soon as possible after ejaculation so that the penis is still somewhat erect. At this time, keep the penis well clear and away from the woman's body.
6. If the condom breaks or, if for any reason, semen spills or leaks out during use, it is advisable that partners should cleanse themselves wherever contact may have occurred, as soon as possible.
7. To further reduce the chance of a sexually transmitted disease, immediately wash the hands, penis and genitals before and after sexual contact.
8. Store condoms in a cool, dry place.
9. If the rubber material is sticky or brittle or obviously damaged, do not use it.
10. Remember -- never reuse a condom.

B:A9248B

510(k): MAGNUM® PLUS

SUBSTANTIAL EQUIVALENCE STATEMENT

The subject device of this Notification, MAGNUM® PLUS Latex Condom with Spermicidal Silicone Lubricant, is substantially equivalent to the currently marketed MAGNUM® Lubricated Latex condom. The MAGNUM® PLUS Latex Condom with Spermicidal Silicone Lubricant is an addition to the MAGNUM® Lubricated condom product line. It utilizes the same condom latex as the MAGNUM® Lubricated Condom. While the lubricant in both the MAGNUM® and MAGNUM® PLUS products is dimethicone (a silicone), the dimethicone in MAGNUM® PLUS is of a lower viscosity. In addition to the lubricant, the MAGNUM® PLUS has a spermicide, nonoxynol-9, and a thickening agent (b)(4). Both these materials combined with the lubricant comprise the spermicidal silicone lubricant. When applied to the condom, as in the proposed MAGNUM® PLUS Latex Condom with spermicidal silicone lubricant, no deterioration of the physical properties or the efficacy of the latex occurs. ?

Representative physical characteristics of pilot batch condoms with the spermicidal lubricant and preliminary specifications are provided below as compared, where applicable, to ASTM Standard Specifications for Rubber Contraceptives (Condoms), D3492-83. The MAGNUM® PLUS Latex Condom with Spermicidal Silicone Lubricant is designed to meet or exceed ASTM Standard Specifications.

510(k) : MAGNUM® PLUS

DESIGN

- A. Type/Style: The MAGNUM® PLUS Latex Condom has a textured interior surface, reservoir end, a tapered shaped profile, is straight-sided and spermicidal silicone lubricated, which according to ASTM is a Type II, Style 2, Class A condom.
- B. Dimensions: The MAGNUM® PLUS Condom meets the ASTM D 3492-83 specifications for dimensions as illustrated in the following tables. It is to be noted that the draft revision of ASTM D 3492-83 no longer provides a maximum mass or maximum thickness specification.

Table 1 - Length, Width, and Mass

(b)(4)



Table 2 - Condom Thickness

MAGNUM® PLUS

(b)(4)



*Average of 10 condoms
**Maximum thickness to be deleted from ASTM in 1989

510(k) : MAGNUM® PLUS

MATERIAL

- A. Rubber: The MAGNUM® PLUS Latex Condom is manufactured from good quality natural rubber latex, containing no color additive, conforming to ASTM Specification D1076-80 Type I latex. These condoms are manufactured by Fuji Latex Company LTD, 19-1, 3-CHOME, Kanbanishiki-CHO, CHIYODA-KU, Tokyo, Japan and supplied to Circle Rubber, 408 Frelinghuysen Avenue, Newark, New Jersey 07114. Circle Rubber, acting as a broker/agent for Fuji Latex Company, in turn sells the products to Carter-Wallace, Inc. The application of the spermicidal silicone lubricant and final packaging is performed by (b) (4) [REDACTED] a contract manufacturer for Carter-Wallace, Inc. The condom latex for this subject device is the same latex used in the currently marketed MAGNUM® product line.
- B. Lubricant: A silicone based spermicidal lubricant will be applied to the MAGNUM® PLUS Condom. Approximately (b) (4) [REDACTED] gram of spermicidal lubricant is applied in total to the outside of each condom. Based on the tensile strength and elongation accelerated aging data (see Physical Characteristics, page 11), the lubricant is compatible with the MAGNUM® PLUS Latex Condom. The lubricant is the same or similar to other condom spermicidal lubricants and is formulated with three ingredients: dimethicone (a silicone), (b) (4) [REDACTED], and the spermicide active ingredient nonoxynol-9. The formulation for the Silicone Spermicidal Lubricant is provided in Appendix I.

510(k) : MAGNUM® PLUS

The concentration of the spermicide nonoxynol-9 in the lubricant is (b) targeted to a 10% overage when formulated. A 1 gram fill per condom of the 6.5% spermicidal lubricant provides 65 mg of the nonoxynol-9 per condom, the minimum recommended by former Surgeon General Koop. This silicone-based spermicidal lubricant with a (b) concentration of nonoxynol-9 is equivalent to other condom products which provide a similar amount or more nonoxynol-9; for example Lifestyles Nuda Plus (Ansell, Inc.) with 6.6% nonoxynol-9, Lifestyles Extra Strength (Ansell, Inc.) with 6.0% nonoxynol-9, Ramses for Her (Schmid) with 15% nonoxynol-9 and Sheik She (Schmid) with 15% nonoxynol-9.

(b)(4) e l a find ubiquitous application in pharmaceutical and cosmetic formulations and are generally recognized as safe for human use both internally and externally. Although nonoxynol-9 has been reported to have a low potential for irritation, based on animal and human use studies of this product the spermicidal lubricant is expected to present little to no potential source of irritation, and it has been found to be safe for vaginal use by FDA's Advisory Panel on OTC Contraceptives and Other Vaginal Drug Products.

The spermicidal effectiveness of the spermicidal silicone lubricant applied to the MAGNUM® PLUS condom was established according to the International Planned Parenthood Federation (IPPF) Agreed Test for Total Spermicidal Power.

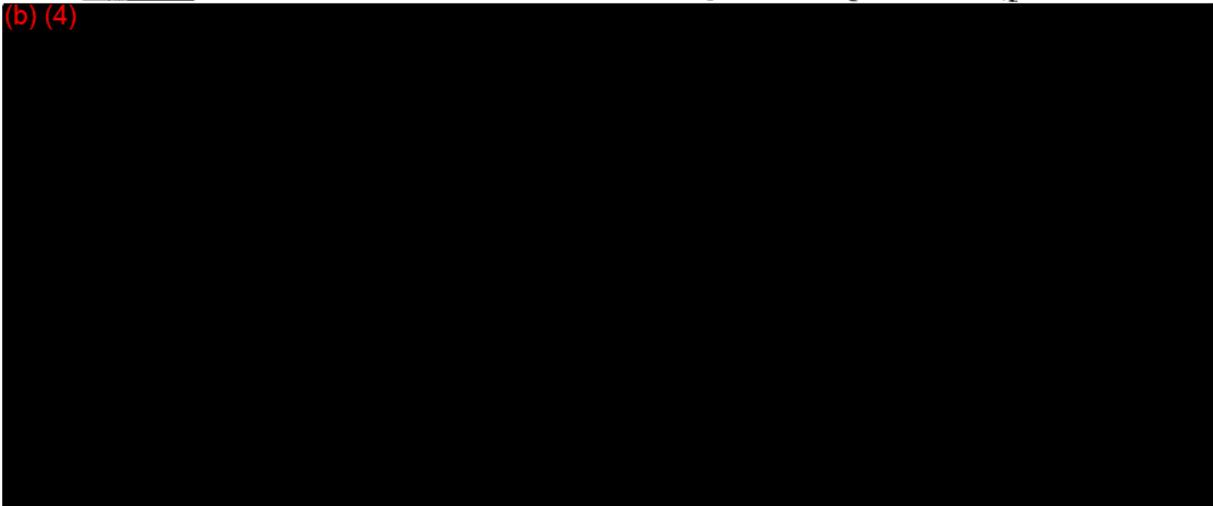
510(k): MAGNUM® PLUS

C. Dressing Material: The dusting agent applied to the MAGNUM® PLUS condoms is [REDACTED], (b)(4) [REDACTED] d [REDACTED], hydrated (b)(4) [REDACTED], or any combination of this depending upon availability and cost of supply at any given time. These dusting agents have been and continue to be used on TROJAN® brand latex condoms; therefore, the MAGNUM® PLUS condom is no different from latex condoms that have been in commercial distribution.

D. Processing Operation

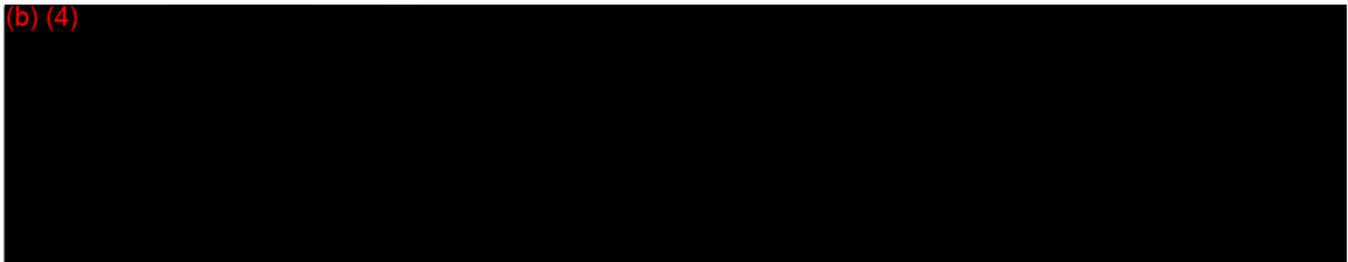
Condoms - The MAGNUM® Condom latex, as previously stated (part A.

(b) (4)



Spermicidal Lubricant - The spermicidal lubricant bulk will be made

(b) (4)



510(k) : MAGNUM® PLUS

PHYSICAL CHARACTERISTICS

A. Tensile Strength, Elongation, and Break Force

The MAGNUM® PLUS Latex Condom with Spermicidal Lubricant meets or exceeds ASTM D 3492-83 specifications for tensile strength and elongation as illustrated in Table 3.

Table 3 - Individually Packaged Spermicidally Lubricated Condoms

	TENSILE STRENGTH (MPa)	ELONGATION AT BREAK (%)
MAGNUM® PLUS		
Pilot EXL-5916*		
Initial		
Aged 7 days @ 70°C		
ASTM D3492-83		
Initial		
Aged 7 days @ 70°C		

(b)(4)

*Average of 10 condoms

B. Leakage

MAGNUM® PLUS Latex Condoms will conform to the ASTM Standard Specification for water leakage of not more than [redacted] es [redacted] [redacted] on [redacted] l [redacted] [redacted] [redacted])

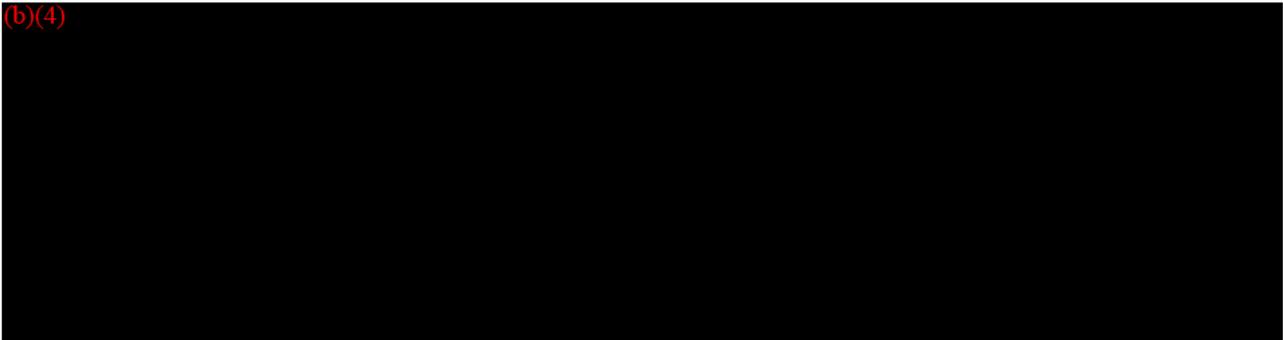
510(k) : MAGNUM® PLUS

OTHER TESTING

Packaged production condoms incorporating the spermicidal lubricant were also subjected to the following tests during product research and development for informational purposes. The ASTM Standard Specifications for Rubber Contraceptives (Condoms), D 3492, do not apply to these tests.

A. Air Burst Test:

(b)(4)



B. Expiration Date Stability Testing

Based on laboratory stability studies on production material, a two (2) year expiration date will be assigned to the spermicidal lubricant.

510(k) : MAGNUM® PLUS

PACKAGING

The MAGNUM® PLUS Latex Condoms with Spermicidal Silicone Lubricant will be packed in a manner equivalent to other MAGNUM® Lubricated condoms.

- A. Primary Packaging: Each condom will be packaged into a unit container consisting of a hermetically sealed, polyester laminate/metalized polyester laminate/low density polyethylene pouch as currently used with the MAGNUM® Lubricated condom. The unit container labeling is pre-printed on the pouch. (See page 2.)
- B. Secondary Packaging: The individually packaged condoms will be packaged into standard paperboard stock cartons of 3 and 12 condoms. The cartons will be preprinted with the labeling described on page 3. The expiration date of the spermicide will be imprinted on each carton prior to packaging.

510(k): MAGNUM® PLUS

ADDITIONAL INFORMATION

The Center for Devices and Radiological Health, Division of Ob-Gyn, ENT, and Dental Devices has been requesting additional information for 510(k) Notifications regarding manufacturing and quality control of condoms which is properly part of Good Manufacturing Practices (GMPs) and which we believe is not within the scope of the Premarket Notification regulations [21 CFR Part 807] and the intent of section 510(k) of the Federal Food, Drug and Cosmetic Act [21 USC 360]. However, to expedite the review of this 510(k) Premarket Notification, the following additional information is provided:

Test Procedures used to Establish Quality: The test procedures used to establish the quality of each batch of MAGNUM® PLUS Latex Condoms with Spermicidal Silicone Lubricant and when these quality control tests are conducted during the manufacturing process are the same for the MAGNUM® PLUS Latex Condom with Spermicidal Silicone Lubricant as they are for the current line of MAGNUM® lubricated condoms.

A quality control test is performed, upon the condoms' arrival from Circle Rubber, at (b)(4) ██████████ in Stewartville, Minnesota. The test procedures are per ASTM D3492-83; sampling per MIL-STD-105D Level II. (Appendix II)

An additional or second quality control test is performed at the Brooklyn Center, Minneapolis, Minnesota, after the spermicidal silicone lubricant has been added and packaging completed. Test procedures are per ASTM D3492-83. (Appendix II)

The spermicidal silicone lubricant bulk is quality control tested by Carter-Wallace, Inc., prior to being applied to the condom. A copy of the specification table (PPS-2012-02) is attached for convenience. (Appendix III)

510(k) : MAGNUM® PLUS

Finished goods received from (b)(4) r [REDACTED] n by Carter-Wallace, Inc., will be quality control tested according to the Specification Table provided in Appendix IV prior to warehousing and distribution.

Any additional information regarding the device within the scope of the 510(k) Premarket Notification requirements that is necessary for the Commissioner to make a finding that the device described herein is substantially equivalent to a device in commercial distribution will be provided upon request by the Commissioner.

CONFIDENTIAL

510(k): MAGNUM® PLUS

Appendix I

Spermicidal Lubricant Formulation
(#CON-108-20)

INGREDIENT

% W/W

(b)(4)



510(k) : MAGNUM® PLUS

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APPENDIX II - Q.C. Specifications and Procedures at (b)(4) [REDACTED],
Stewartville, Minn. for incoming Fuji Condoms

<u>Property</u>	<u>Specification/Procedure</u>		<u>Sample Size</u>
Water Leak	ASTM	D3492-83	Per MIL-STD-105D Level II
Tensile Strength	ASTM	D3492-83	Per MIL-STD-105D Level II
Elongation	ASTM	D3492-83	Per MIL-STD-105D Level II
Dimensions	ASTM	D3492-83	Per MIL-STD-105D Level II
Certificate of Analysis and Compliance to ASTM	ASTM	D3492-83	Per MIL-STD-105D Level II

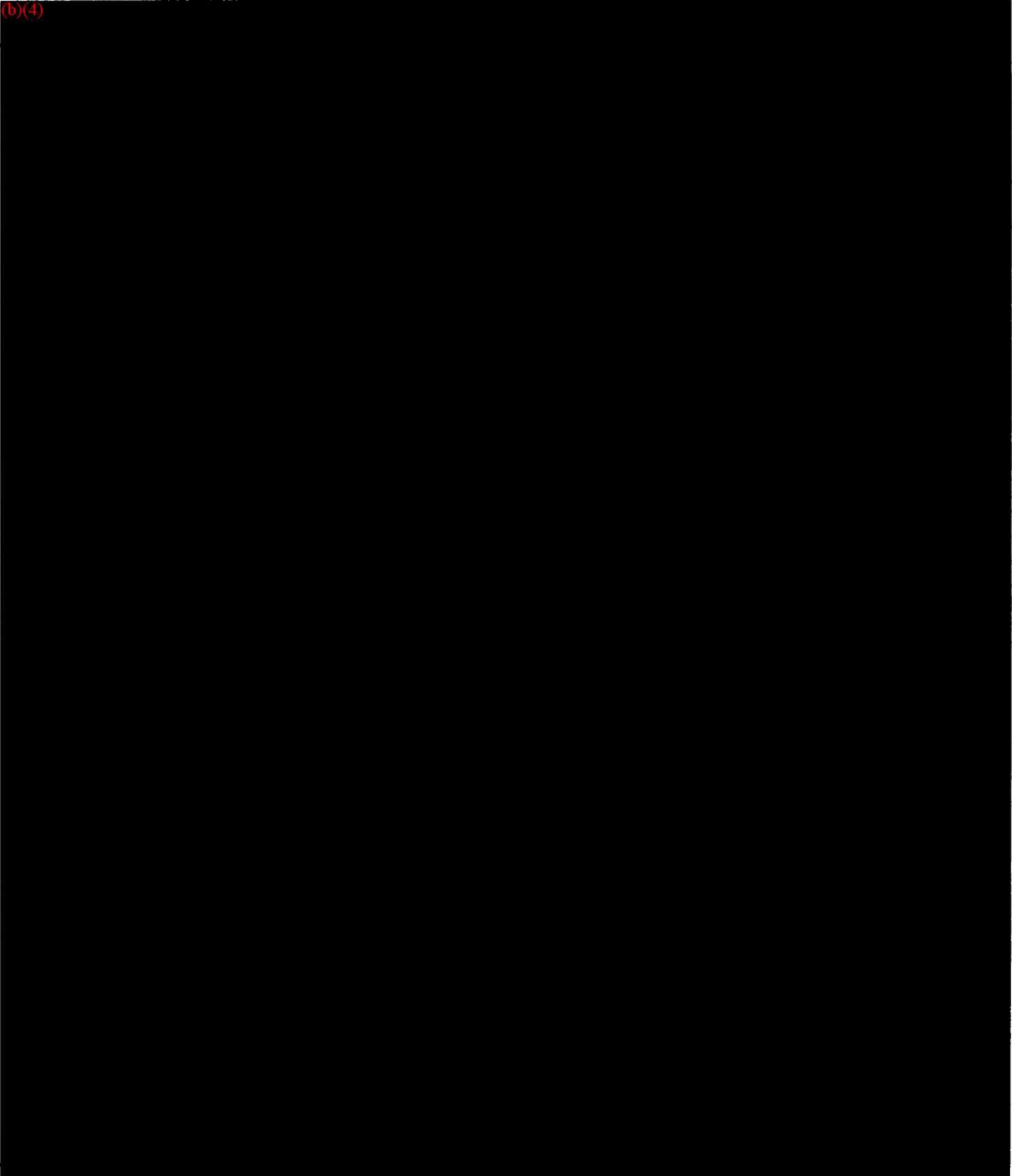
(b)(4)

(b)(4)

(b)(4)



(b)(4)



(b)(4)

(U)(4)

(b)(4)

(b)(4)

(b)(4)

(D)(4)

BEST COPY AVAILABLE

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

22
58

(b)(4)

(b)(4)

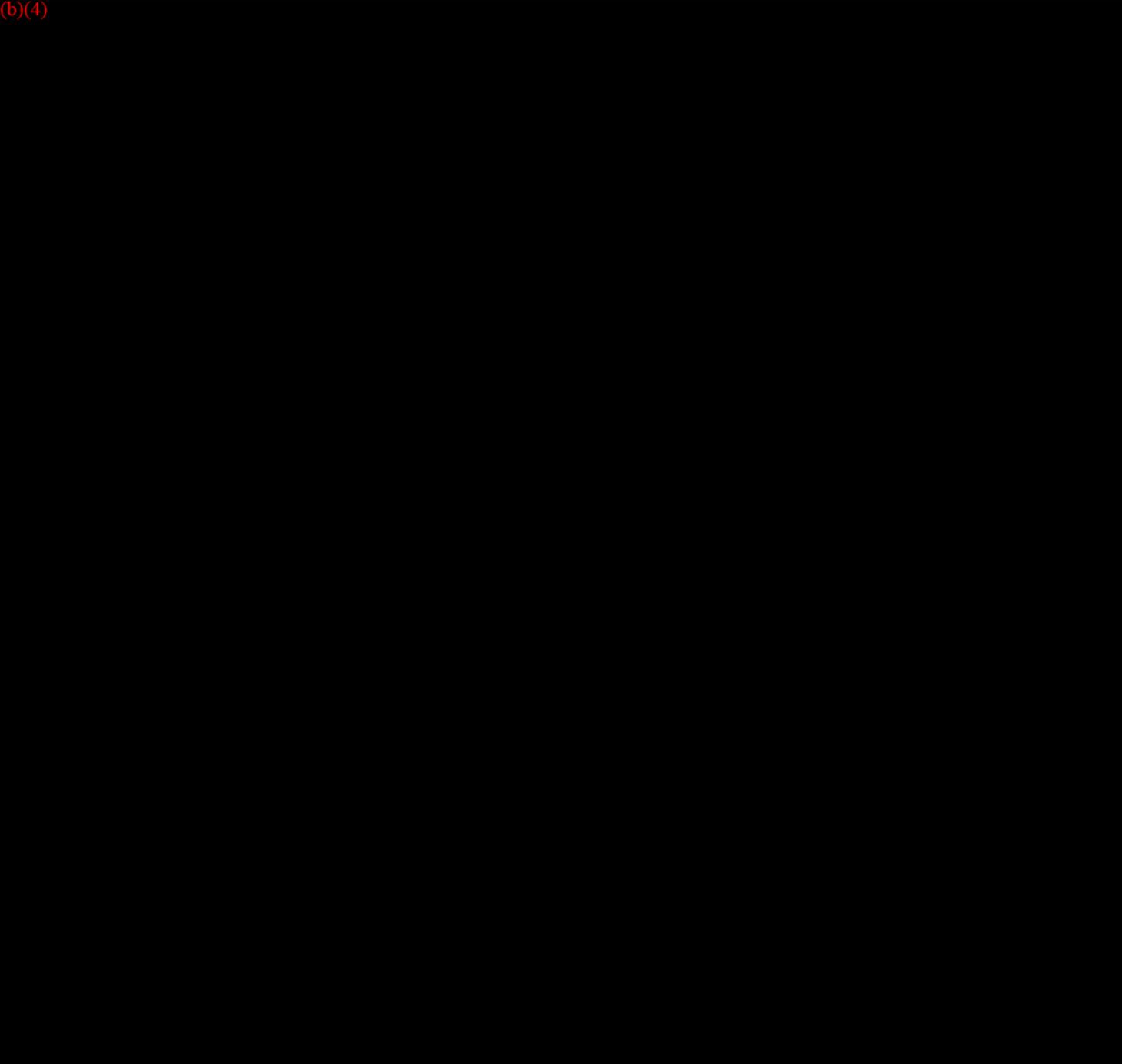
CONFIDENTIAL

510(k) : MAGNUM® PLUS

Appendix IV

TENTATIVE FINISHED GOODS SPECIFICATION TABLE - MAGNUM PLUS

(b)(4)



K895640

Jones, Edwena

From: Andrews, Sharon M
Sent: Tuesday, September 11, 2012 9:15 PM
To: Jones, Edwena
Cc: Blyskun, Elaine
Subject: RE: updating Device Listing

Hi Edwena,

I looked up both K912901 and K895640 in IMAGE, and the condoms cleared in both submissions contain N-9. The SE letters for both devices also include the regulation number for condoms with N-9 (21 CFR 884.5310). Therefore, I agree that LTZ (condom with nonoxynol-9) should be added as a product code for both 510(k)s.

Please let me know if you need anything else.

Thank you.

Sharon

From: Jones, Edwena
Sent: Monday, September 10, 2012 10:24 AM
To: Andrews, Sharon M
Subject: FW: updating Device Listing

Hi Sharon,

The sponsor is inquiring about a product code for their cleared product. If you agree that LTZ should be added please let me know. I will update the database, since the clearance was prior to adding the product codes to the SE letters, we will not have to generate a letter.

Please let me know if you need any additional assistance.

Thank you
 Edwena

From: Vescovi, Karen [<mailto:Karen.Vescovi@churchdwright.com>]
Sent: Thursday, July 12, 2012 3:07 PM
To: CDRH Registration and Listing; Jones, Edwena
Subject: RE: updating Device Listing

Thank you, Doug.

Dear Edwena Jones, please see e-mail chain below for history of request.

We have two 510(k)s that the products are classified as HIS (latex condom) when K912901 should also have included the product code LTZ for a Latex Condom with Spermicidal Lubricant, this 510(k) was cleared for both. The other 510(k) K895640 was submitted and cleared for a Latex Condom with Spermicidal Lubricant but is classified with product code HIS.

I'm not sure if this is just an oversight or if at that time all Condoms were classified as "HIS", just as previously only the product codes were listed not the individual product. Please advise if this can be adjusted so we can update our listing for these product.

Regards,
 Karen

Karen Vescovi
 Regulatory Specialist
 Church & Dwight Co., Inc.
 469 North Harrison Street
 Princeton, NJ 08543

(609) 279-7715 phone
 (609) 497-7179 fax
karen.vescovi@churchdwright.com

From: CDRH Registration and Listing [<mailto:reglist@CDRH.FDA.GOV>]
Sent: Thursday, July 12, 2012 2:43 PM
To: Vescovi, Karen; CDRH Registration and Listing
Subject: RE: updating Device Listing

9/12/2012

Karen Vescovi,

If you feel that a product code has been omitted from your 510K, please contact Edwena Jones at the Office of Device Evaluation at Edwena.Jones@fda.hhs.gov

The Medical Device Registration and Listing Program is separate from the 510(k) program. I would recommend that you contact the FDA Center for Devices and Radiological Health's Division of Small Manufacturers, International and Consumer Assistance (DSMICA) for help in resolving this matter. They can be reached by phone at (800) 638-2041 or 301-796-7100, or by email at dsmica@fda.hhs.gov.

Additional information can be found at the 510(k) website at:

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm>.

Please note: General information regarding Registration and Listing can be found on our web site:

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/default.htm>

This is an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

Thank you,
Doug Zveare

From: Vescovi, Karen [<mailto:Karen.Vescovi@churchdwright.com>]
Sent: Thursday, July 12, 2012 1:48 PM
To: CDRH Registration and Listing
Subject: RE: updating Device Listing

Hi Doug, thank you for your expedited response.

I understand that you cannot just "add" a product code but the 510(k) associated with this product was cleared under 21 CFR 884.5300 and 21 FR 884.5310 for latex condom with both lubricated and spermicidal versions, I have attached the FDA Clearance Letter dated February 3, 1992.

There also seems to be a mistake with another 510(k) K895640, for Magnum Plus Latex Condom with Spermicidal Silicone lubricant, cleared January 23, 1990 according to FDA website search it also is not recorded as a spermicidal LTZ product code it too is listed under HIS 21 CFR 884.5300.

Any help is greatly appreciated, as K912901 is for both HIS and LTZ and K895640 is a 510(k) for a Latex Condom with Spermicidal Lubricant..

Regards,
Karen

Karen Vescovi
Regulatory Specialist
Church & Dwight Co., Inc.
469 North Harrison Street
Princeton, NJ 08543

(609) 279-7715 phone
(609) 497-7179 fax
karen.vescovi@churchdwright.com

From: CDRH Registration and Listing [<mailto:reglist@CDRH.FDA.GOV>]
Sent: Thursday, July 12, 2012 1:21 PM
To: Vescovi, Karen; CDRH Registration and Listing
Subject: RE: updating Device Listing

Karen Vescovi,

Product code LTZ is a 510(k) submission. If you wish to list product code LTZ you will need to submit a 510(k) and wait for its approval. You cannot add this product code to another 510(k) listing. When a 510(k) is approved FDA assigns the appropriate product code(s). The assigned product code(s) may not be changed or new product codes added.

Please note: General information regarding Registration and Listing can be found on our web site:

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/default.htm>

This is an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

Thank you,

Doug Zveare

From: Vescovi, Karen [<mailto:Karen.Vescovi@churchdwright.com>]
Sent: Thursday, July 12, 2012 12:42 PM
To: CDRH Registration and Listing
Subject: updating Device Listing

Please advise how to update a device listing for K912901--(D064747, Condom) currently it is listing a Lubricated Condom HIS, but need to add Spermicidal Condom product code LTZ to listing, S10(k) covered both. I've tried to update, cancel and re-enter but cannot add this information.

Your assistance is greatly appreciated. You can reach me at the numbers below.

Regards,
Karen

Karen Vescovi
Regulatory Specialist
Church & Dwight Co., Inc.
469 North Harrison Street
Princeton, NJ 08543

(609) 279-7715 phone

(609) 497-7179 fax

karen.vescovi@churchdwright.com

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