Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

MAY - 4 1995

K922688

510(k) Summary
Statement of Safety and Effectiveness

I.	**Submitter's Name:**	Apex Medical Technologies, Inc. 10064 Mesa Ridge Court, Suite 202 San Diego, CA 92121
II.	**Submitter's Phone Number:**	(619) 535-0012
III.	**Contact Person:**	Alice A. DePaul, Vice President
IV.	**Date of Preparation:**	January 27, 1993
V.	**Name of Device:**	"Polyurethane Condom"
VI.	**Trade or Proprietary Name:**	"Avanti Condom"
VII.	**Common or Usual Name:**	Condom
VIII.	**Classification Name:**	Condom
IX.	**Predicate or legally marketed device or devices to which substantial equivalence is claimed:**	Currently marketed latex condoms and the polyurethane condom described in 510(k) Premarket notification # K902936/A, accepted by FDA on March 6, 1991.

X. General Description of the diseases or conditions the device will diagnose, treat,prevent, cure or mitigate, including a description of the patient population for which the device in intended:

This condom is intended to aid in the prevention of pregnancy, and is intended to help prevent the transmission of sexually transmitted diseases. The patient population for which this product is intended is as follows: people who engage in vaginal intercourse who wish to reduce the likelihood of becoming pregnant and/or contracting sexually transmitted disease(es). This condom is not intended for people who expect absolute protection. People requiring absolute protection from pregnancy and/or sexually transmitted diseases should consult their physicians for alternatives.

XI. Description of Device:

This polyurethane condom is a combination contraceptive and disease prevention device which functions by acting as a barrier to the transfer of semen and/or infective microorganisms known to cause sexually transmitted diseases. This barrier protection is intended to be effective for vaginal intercourse only. The basis for function of this device is based upon the fact that these condoms are essentially pore-free and will not allow for the passage of spermatozoa or disease organisms between sexual partners during vaginal intercourse.

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

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The main cylindrical portion of this condom is produced from a material called polyurethane. The open end of the condom has a ring made from a proprietary synthetic rubber material which is softer than the polyurethane to provide for added comfort to the user.

XII. Description of Non-Clinical Tests and Their Results

The results of physical properties testing support the substantial equivalency claims. The results of the physical properties tests show the polyurethane condoms to have higher tensile strengths, and air burst pressures than currently marketed latex condoms. Average air burst pressure for this polyurethane condom was shown to be 5.50 kilopascals, compared to 1.34 kilopascals for standard thickness latex condoms and 1.72 kilopascals for extra strength latex condoms. The average tensile strength for this polyurethane condom was shown to be 61.0 megapascals, compared to 20.32 megapascals for standard thickness latex condoms and 25.08 megapascals for extra strength latex condoms.

The release criteria for this condom is based upon the water leakage test described in ASTM Standard Specification for Rubber Contraceptives (Condoms) D 3492 and will be set to a level of AQL=0.4 General Inspection Level I, (Mil/Ansi Spec 105), compared to AQL=0.4 General Inspection Level I, (Mil/Ansi Spec 105) for standard latex condoms and extra strength latex condoms.

XIII. Conclusions drawn from nonclinical and clinical tests that demonstrate the device is "safe, effective and performs as well or better than the currently legally marketed device".

Based upon superior physical properties, and based upon product release criteria, this condom is expected to be substantially equivalent or superior to currently marketed latex condoms.

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

Records processed under FOIA Request # 201[illegible]976; Released by CDRH on 09-03-2015

JUL 5 1996

London International U.S. Holdings, Inc.

K922688/A5

1819 Main Street ▪ Sarasota, Florida 34236 ▪ Mailing Address: P.O. Box 4703 ▪ Sarasota, Florida 34230-4703
Telephone: (941) 365-1600 ▪ FAX: (941) 366-3640

Phyliss M. Barber
Vice President
Regulatory Affairs

RECEIVED
8 JUL 96 15 14
FDA/CDRH/ODE/DMC

July 3, 1996

Dr. Lillian Yin
Food and Drug Administration
Bureau of Medical Devices
9200 Corporate Blvd., HFZ-470
Rockville, MD 20850

Dear Lillian:

Since the clearance of the polyurethane condom under K922688, the manufacturing facility has expanded the process for its polyurethane condoms marketed under the various Avanti® trade names to include the specifications stated in K922688. An example of the labeling for these condoms is attached.

Sincerely,

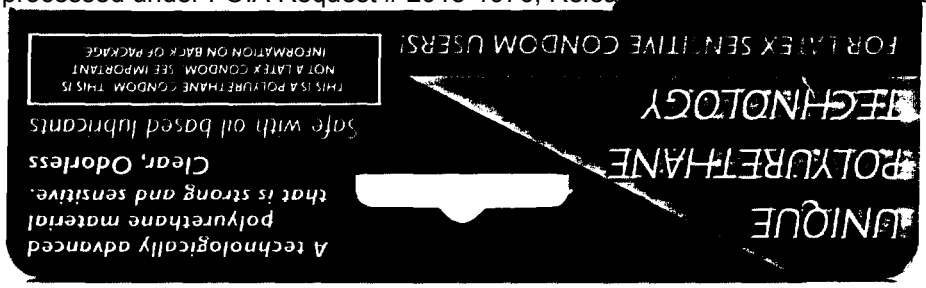
Phyliss M. Barber
Vice President
Regulatory Affairs
LONDON INTERNATIONAL U.S. HOLDINGS, INC.

attachment

PMB/cs

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015



No. 570

Directions for opening package:
Press along perforation. Remove top panel and discard. Package can be easily reclosed. (Patent No. 4,291,807)

Instructions printed inside.
Instrucciones en Español impresas adentro

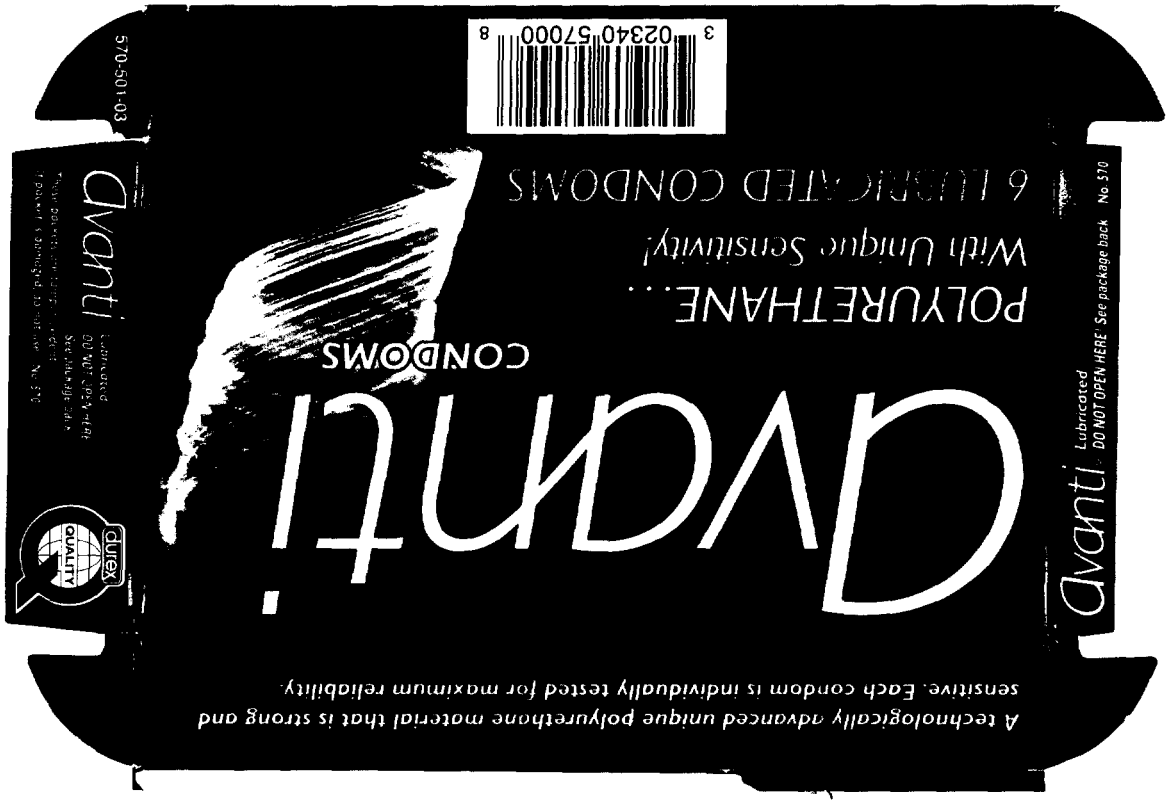
IMPORTANT CONSUMER INFORMATION

- ***You may use this polyurethane condom if you or your partner are allergic to latex.***
- ***The risks of pregnancy and sexually transmitted diseases (STDs), including AIDS (HIV infection), are not known for this condom. A study is being done.***
- ***There are laboratory tests on this polyurethane material. These tests show that organisms even as small as sperm and viruses like HIV cannot pass through it.***
- ***Latex condoms for men, if used correctly with every act of vaginal intercourse, are highly effective at preventing pregnancy, as well as STDs, including AIDS (HIV infection).***

Storage: Avoid prolonged storage of condoms at temperatures in excess of 100 degrees Fahrenheit– storage for short periods of time at this temperature will not be harmful to the product. Avoid any storage close to a hot radiator, hot air duct or similar object. Any use of condoms for other than vaginal intercourse can increase the potential of damage to the condom.

For maximum benefits, it is important to follow the instructions printed on the inside of the carton. 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 STD's. Therefore, the condom should be applied each and every time before such contact occurs.

Distributed by London International U.S. Holdings, Inc.
Schmid Laboratories Division, Sarasota, FL 34230-4703
Duron®, a trademark for a unique polyurethane film



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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

No. 580

Directions for opening package:
Press along perforation. Remove top panel and discard. Package can be easily reclosed. (Patent No. 4,291,807)

Instructions printed inside.
Instrucciones en Español impresas adentro.

IMPORTANT CONSUMER INFORMATION

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- ***Latex condoms for men, if used correctly with every act of vaginal intercourse, are highly effective at preventing pregnancy, as well as STDs, including AIDS (HIV infection).***

Storage: Avoid prolonged storage of condoms at temperatures in excess of 100 degrees Fahrenheit– storage for short periods of time at this temperature will not be harmful to the product. Avoid any storage close to a hot radiator, hot air duct or similar object. Any use of condoms for other than vaginal intercourse can increase the potential of damage to the condom.

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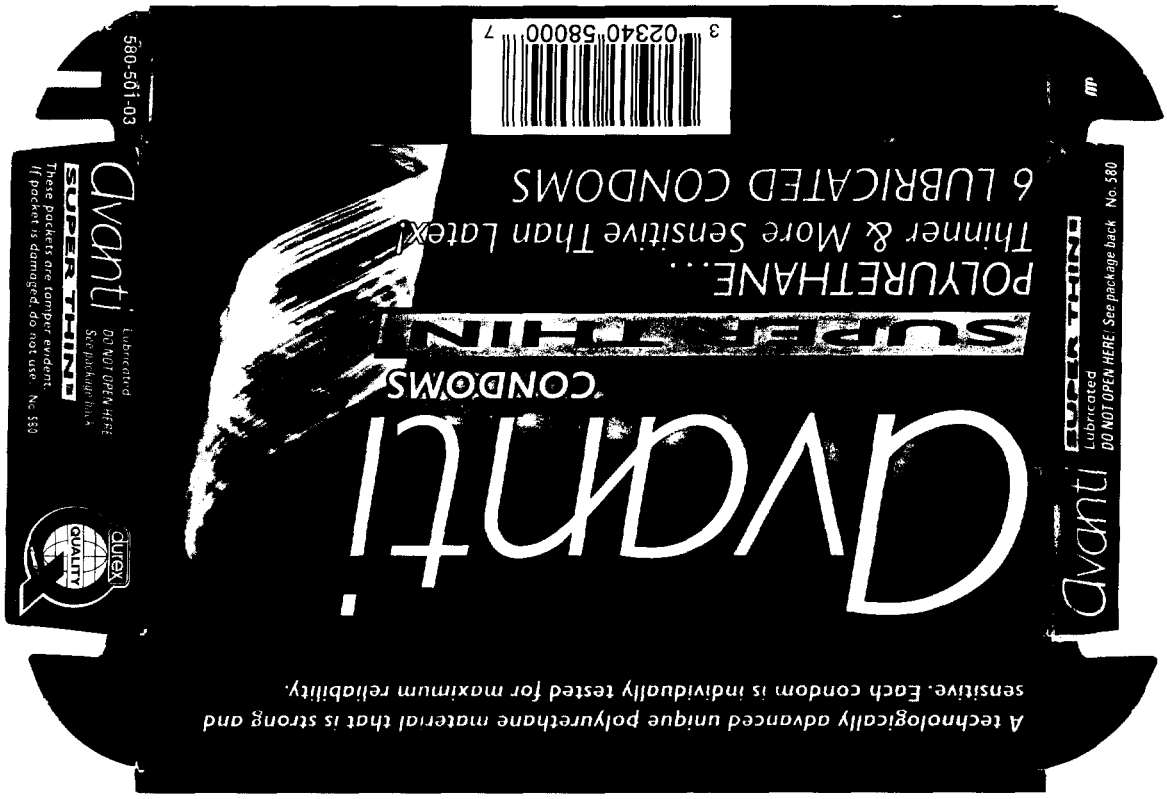
Duron®, a trademark for a unique polyurethane film.



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

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DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 16 1997

William D. Potter
Group Scientific Affairs Director
London International Group plc
35 New Bridge Street
London EC4V 6BJ
ENGLAND

Re: K922688
Device Name: Durex Avanti
Dated: September 25, 1997
Received: September 30, 1997

Dear Mr. Potter:

We have received the information in your letter dated September 25, 1997, regarding the 510(k) notification K922688 previously submitted for the device referenced above requesting a change in the indications for use. Based solely on the information that you have provided, it appears that you have significantly changed or modified the design, components, method of manufacture, device labeling, or intended use of the device referenced above (see 21 CFR 807.81(a)(3)). You will need to submit a new 510(k) and receive Food and Drug Administration clearance prior to marketing your device with these changes. Your new 510(k) should include a copy of the Final Report for Project Number NO1-HD-3109 "Study of the Efficacy, Acceptability, and Safety of Non-Latex (Polyurethane) Male Condom" and final reports from any other studies you intend to use to support your proposed labeling changes. In addition, we will be contacting you regarding the device labeling proposed in your letter. Your letter referenced above will be added to the original 510(k) file with a copy of this letter. If you have any questions, please contact Mr. Colin M. Pollard at (301) 594-1180 or the Division of Small Manufacturers Assistance at (800) 638-2041 or (301) 443-6597.

Sincerely yours,

Lillian Yin

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat, and
Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

William D. Potter
Group Scientific Affairs Director
London International Group plc
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Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat, and
Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

cc: HFZ-470 DRAERD
HFZ-401 DMC

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
Z470	Kuenstner	10/10						
Z470	Pollard	10/10/97						

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food And Drug Administration

Memorandum

Reviewed by JMK 5/1/95

Date: 10/1/97

From: Document Mail Center (HFZ-401)

Subject: Premarket Notification Number(s) K952168/A1

To: Division Director, CD/DRHR

The attached information has been received by the 510(k) Document Mail Center (DMC), on the above referenced 510(k) submission. Since a final decision has been rendered, this record is officially closed

Please review the attached document and return it to the DMC, with one of the statements checked below. Feel free to note any additional comments below.

Thank you for your cooperation.

_____ Information does not change status of the 510(k); no other action required by the DMC; please add to the image file. [THE DIVISION SHOULD PREPARE A CONFIRMATION LETTER - AN EXAMPLE IS AVAILABLE ON THE LAN (K25). THIS DOES NOT APPLY TRANSFER OF OWNERSHIP, PLEASE BRING ANY TRANSFER OF OWNERSHIP TO POS].

X Additional information requires a new 510(k), however the information submitted is incomplete. Notify the company to submit a new 510(k). [THE DIVISION SHOULD PREPARE THE K30 LETTER ON THE LAN.]

_____ Additional information requires a new 510(k); please process. [THIS INFORMATION WILL BE MADE INTO A NEW 510(K)].

_____ No response necessary (e.g., hard copy of fax for the truthful and accuracy statement or 510(k) statement)

This information should be returned to the DMC within 10 working days from the date of this memorandum.

Reviewed by J.M. Kuemisk HFZ-470

Date 10/10/97

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

Records processed under FOIA Request # 20[redacted]1976; Released by CDRH on 09-03-2015

London International Group plc

35 New Bridge Street, London EC4V 6BJ. Telephone: 0171-489 1977 Direct Line: 0171-716 6295 Fax: 0171-329 4268

W. D. Potter
Group Scientific Affairs Director

CONFIDENTIAL

Dr L Yin, Ph.D
Director, DRAERD
Food & Drug Administration
HFZ-470
9200 Corporate Boulevard
Rockville
MD 20850
USA

RECEIVED
SEP 30 2 03 PM '97
FDA/CDRH/ODE/DMC

cc: C Pollard, FDA

25 September 1997

Dear Lillian

Re: **510(K) Application**
K922688

As I agreed I now attach a draft of the revised pack copy and information leaflet that we propose to submit in a 510K for Avanti K922688.

Please note that the comparative efficacy rates reported in the leaflet for Durex Avanti and Durex Ramses have been calculated from the data in the (b) (4) report using the formulae.

(b) (4)

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

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(b) (4)

[redacted]

As we are anxious to progress the 510K I would appreciate receiving any comments you have on the labelling within the next few weeks. As soon as we have your comments we will then submit the 510K for the change in labelling.

Kind regards

Yours sincerely

W D Potter

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

(b)(4) Test Data

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

(b)(4) Test Data

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(b)(4) Test Data

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DUREX AVANTI PACK COPY (RETAIL PACKS 2s & 5s)

FRONT PANEL

World's first polyurethane male condom

DUREX® Avanti®

The most natural feeling

Thinner and more sensitive than regular latex condoms

2/5 Lubricated Polyurethane Condoms

FIFTH PANEL (HANGING DEVICE)

Revolutionary non-latex condoms

Helps Protect Against Pregnancy, HIV (AIDS) & STDs

SIDE ONE - LEFT

DUREX® AVANTI®
100% TESTED
DO NOT OPEN HERE! See package back.
No. XXX [for 2 pack] No. XXX [for 5 pack]
PART NO. RL XXX [for 2 pack]
RL XXX [for 5 pack]

[Leave space for lot #, Manufacturer ID, "Manufactured in the UK" and Expiration dates to be printed on the package in Dothan, AL.]

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

SIDE TWO - RIGHT

DUREX® AVANTI®
SUITABLE FOR LATEX SENSITIVE USERS
100% TESTED
DO NOT OPEN HERE!! See package back. These packages are tamper evident.
If package is damaged, do not use.
No. XXX [for 2 pack] No. XXX [for 5 pack]

SIDE THREE - TOP

Unique non-latex material that is sensitive, clear, odorless, and safe with oil based lubricants.
Each condom is individually tested for maximum reliability.

SIDE FOUR - BOTTOM

Bar Code [XXX for 2 pack] [XXX for 5 pack]

BACK PANEL

DUREX® AVANTI®
from Durex®, the world's leading condom brand, with over 70 years of quality experience.

Durex® Avanti® is the world's first polyurethane male condom.

UPPER LEFT CORNER No. XXX [for 2 pack] No. XXX [for 5 pack]

Instrucciones en Español impresas adentro.

Durex Avanti condoms are made from a revolutionary polyurethane material that is stronger than latex, therefore the condom can be made much thinner to give you the most natural feeling.
Durex Avanti condoms are transparent, reservoir tipped and lubricated with a gentle non-spermicidal lubricant. Unlike natural rubber latex condoms, *Durex Avanti* condoms may be used with oil based lubricants as well as water based lubricants.

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

DRAFT **AVANTI PACK COPY**
USA COPY **FULL CLAIMS** 23 September, 1997

Directions for opening package:
Press along perforation. Remove top panel and discard. Package can be easily reclosed
(Patent No. 4,291,807).

[Durex Quality Seal] Quality with out compromise is the *Durex* promise.

For maximum benefits, it is important to follow the instructions in the information leaflet inside of the carton. Failure to do so may result in the loss of the benefits of a condom.

When properly used, *Durex Avanti* condoms help protect against unwanted pregnancies and catching or spreading many sexually transmitted diseases (STDs) such as syphilis, gonorrhea, chlamydial infections, genital herpes and AIDS. However, they cannot eliminate the risk. No method of contraception can provide 100% protection against pregnancy or the transmission of HIV(AIDS) and STDs. See information leaflet inside.

Non-vaginal use of condoms increases the risk of them slipping or being damaged.

Store in a cool, dry place away from direct sunlight.

Durex, Avanti and *Durex* Seal of Quality are trademarks of the LI group.

Distributed by Durex Consumer Products, Norcross, GA 30092
www.durexavanti.com

CONFIDENTIAL

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

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AVANTI LEAFLET COPY [SIX PANELS]

OUTSIDE THIRD PANEL

DUREX® Avanti® (logo)

Revolutionary polyurethane condoms

PLEASE READ THIS LEAFLET CAREFULLY

INSIDE FIRST PANEL

DUREX® Avanti® (logo)

Durex Avanti is the world's first polyurethane male condom. It is made from a revolutionary polyurethane material that is stronger than latex, therefore the condom can be made much thinner to give you the most natural feeling. *Durex Avanti* condoms are lubricated with a gentle non-spermicidal lubricant. The *Durex Avanti* condom has many advantages over a standard latex condom:

- Suitable for latex sensitive users
- Thinner and more sensitive
- Clear
- Odorless
- Can be used with oil based lubricants as well as water based lubricants
- Slightly larger for a more comfortable fit

Durex condoms are tried and trusted by millions of people worldwide. Indeed our commitment to quality has made *Durex* the world's leading condom brand.

[Durex Quality Seal] Quality without compromise is the *Durex* promise.

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

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INSIDE SECOND/THIRD PANEL

IMPORTANT
HOW TO USE A CONDOM

Put the condom on after the penis is erect and prior to intimate contact, because lesions, pre-ejaculated secretions, semen, vaginal secretions, saliva, urine, and feces can contain sexually transmitted disease (STD) organisms. To further reduce the chance of spreading or acquiring an STD, immediately wash the hands, penis and surrounding area and external vaginal area before and after sexual contact.

To remove the condom, tear open the end of the foil package carefully. Do not unroll the condom before putting it on as this may damage the condom or make it more difficult to use properly. Rough handling, jewelry or fingernails can damage the condom and reduce its effectiveness. Do not use condom if foil package is damaged or open, or if the material is sticky or brittle or obviously damaged.

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 towards the base of the penis.

Put the condom on the head of the penis and unroll it all the way to the base. If the condom does not unroll to the base of the penis, it has been put on incorrectly and should be discarded. Make sure the condom stays in place during sex; if it rolls up, roll it back into place immediately. If the condom comes off completely, then a new condom must be used before sex continues. If additional lubricant is desired, oil-based and water-based lubricants can be used with Durex Avanti.

After ejaculation, carefully withdraw the penis while it is still erect. Hold onto the rim of the condom as you withdraw so that the condom does not slip off. Remember to keep both the penis and the condom clear from contact with your partner's body. Do not reuse a condom. Use a new condom every time you have sexual intercourse.

Discard the used condom hygienically (not down the toilet). If the condom breaks, or for any reason semen spills or leaks out during use, both partners should cleanse themselves wherever contact may have occurred as soon as possible.

REMEMBER NEVER USE A CONDOM MORE THAN ONCE

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

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OUTSIDE FIRST/SECOND PANELS

Durex manufactures a wide range of condoms specifically designed to offer a comprehensive choice to suit your needs and make condom use more pleasurable.

In addition to the unique *Durex Avanti* condoms contained in this pack, the *Durex* range of natural rubber latex condoms are also available.

Storage: Store condoms in a cool dry place, away from sunlight. The condom should not be removed from the foil pack until ready for use. Do not store on furniture - lubricant may leak and damage furniture.

Contraceptive Efficacy: The contraceptive efficacy of *Durex Avanti* has been determined in a clinical study to be equivalent to *Durex Ramses* latex condoms.

The typical use and consistent use (ie. condom used every time) pregnancy rates per 100 women years for *Durex Avanti* are given in the table below along with published values for other methods of contraception.

	Pregnancies/100 Women Years	
	Typical Use	Consistent Use
Durex® Avanti® Condom	10.1*	6.2*
Durex® Ramses® Sensitol® (Latex) Condom	12.5*	2.3*
Published result for Regular Latex Condoms	12	3
Polyurethane Female Condom	21	-
Vaginal Sponge	17	-
Spermicide Alone	21	-
Periodic Abstinence	20	-
No Method	85	-

* LIG Estimate - To be agreed with LARFPC

Breakage Rate: Studies have determined the breakage rate for *Avanti* to be as follows:

	Breakage Rate
Durex® Avanti®	1.8% - 4.0%
Durex® Ramses® Sensitol® (Latex)	0.4% - 1.3%
Published result for Regular Latex Condoms	1.3% - 6.7%

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

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Precautions: Non-vaginal use of any condom can increase the potential of it slipping or being damaged, please consult you physician. If there are lesions, open sores, viral warts, or other abnormalities noticeable on either person, you should avoid sexual intercourse and consult a physician. If you experience burning or irritation of the vagina or penis, discontinue use, wash the affected area thoroughly and consult your physician.

Other: When properly used, Durex Sheik condoms may help reduce the risk of unwanted pregnancies and catching or spreading many sexually transmitted diseases (STDs) such as syphilis, gonorrhea, chlamydial infections, genital herpes, and AIDS. However, it cannot eliminate the risk. No method of contraception can provide 100% protection against pregnancy or the transmission of HIV or STDs.

If after making love you are concerned for whatever reason that you or your partner may have become pregnant, consult a physician immediately.

Durex, Avanti and *Durex* Seal of Quality are trademarks of the LI group.

Distributed by Durex Consumer Products, Norcross, GA 30092
www.durexavanti.com
Part No. XXX

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

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 17 1998

Mr. William D. Potter
Group Scientific Affairs Director
London International Group, plc
35 New.Bridge Street
London EC4V 6BJ

Re: K922688
Durex Avanti™ Polyurethane Condom
Dated: November 24, 1997
Received: December 2, 1997

Dear Mr. Potter:

We have received the information in your letter dated November 24, 1997, regarding the 510(k) notification K922688 previously submitted for the device referenced above. However, as you informed us by telephone, subsequent to the submission of your letter, London International Group plans to continue product development of the Avanti™ condom and will leave the current labeling unchanged, i.e., for latex sensitive users only.

Notwithstanding your decision to continue marketing the Avanti™ condom per the original labeling limitations (enclosure), any future labeling change, such as the recent proposal in your November 24, 1997, letter, would need to be reviewed by the Food and Drug Administration (FDA). Such a labeling revision to remove the original labeling restrictions (latex sensitive users only) and target a general population will significantly change the device labeling and intended use of your condom (see 21 CFR 807.81(a)(3)).

If you intend to make such labeling changes at some point in the future, you will need to submit a new 510(k) and receive FDA clearance prior to marketing the Avanti™ condom with the new labeling. This 510(k) should also contain full reports and analyses from the two contraceptive efficacy studies of the Avanti™ condom, as well as reports from all slippage and breakage studies. Your analyses should fully compare the Avanti™ condom to latex condoms now available on the market, and these should support your proposed labeling changes.

Your letter referenced above will be added to the original 510(k) file with a copy of this letter. If you have any questions, please contact Mr. Colin M. Pollard at (301) 594-1180 or the Division of Small Manufacturers Assistance at (800) 638-2041 or (301) 443-6597.

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

NOV 21 1994

See Attachment for Addressees

This letter is a follow up to the labeling requirements fax'd to you last week for condoms made of polyurethane and other new materials (enclosure). As you know, the agency developed this policy, with input from the industry, to permit marketing of condoms that can be used by people allergic to latex, who otherwise have no alternative for protection from sexually transmitted diseases (STDs).

Although such new condoms will have undergone extensive laboratory testing and will have been evaluated for slippage and breakage, their effectiveness in actual use has not been tested. Normally, such testing would be required before a product is cleared for marketing. However, because of the potential risk to latex-sensitive people who might forego using a condom or mistakenly depend on a lambskin condom to provide STD protection, the FDA decided to clear these new condoms before completion of clinical trials that would establish in-use comparison to latex condoms.

While the clinical trials are ongoing, manufacturers will be required to state on the labeling that - as specified in the enclosure - the condom is intended to be used only when either partner is allergic to latex. Manufacturers will also be required to include a caution that, although laboratory testing has shown that particles as small as sperm and viruses will not pass through the material, clinical trials to assess effectiveness in preventing pregnancy and STDs have not been completed.

The enclosure specifies the language and format for both the principal display panel and the back panel of the retail package. This required information shall be displayed no less prominently than other consumer information on the package, such as the storage information or precautions.

This same required consumer labeling shall also be provided with any package insert.

As discussed at the October 4, 1994, FDA/Industry meeting, several 510(k)s for non-latex condoms were approved in previous years although no products were in commercial distribution. We have worked with the one manufacturer who has chosen to proceed to marketing at this time on interim labeling pending our decision on the wording contained in this communication. This manufacturer, London International, has agreed to amend their labeling to conform with that of other manufacturers as soon as such wording was available. In addition, their foil packaging contains older claims which will also conform to the new labeling requirements before the end of 1994.

We wish to thank you for your assistance in the development of this labeling and your participation in our recent meeting.

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

If you have any further questions on applying this labeling guidance to your condom for the completion of your 510(k) premarket notification, you may contact Mr. Colin M. Pollard, at 301-594-1180.

Sincerely yours,

Susan Alpert, Ph.D., M.D.
Director
Office of Device Evaluation
Center for Devices
and Radiological Health

Enclosure

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

3

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

INTERIM LABELING REQUIREMENTS FOR CONDOMS MADE FROM NEW MATERIALS

I. Principal Display Panel

The principal display panel (21 CFR §801.60) must display the following:

"For Latex Sensitive Condom Users"

This is a [Blank] condom. This is <u>not</u> a latex condom. See Important Information on Back of Package.

II. Back Panel

The following *Important Consumer Information* must be placed on the back panel of the retail package, as well as within the package insert and with any promotional material:

Important Consumer Information: [Bold]

You may use this [Blank] condom if you or your partner are allergic to latex.

You should know:

- The risks of pregnancy and sexually transmitted diseases (STDs), including AIDS (HIV infection), are not known for this condom. A study is being done.

- There are laboratory tests on this [Blank] material. These tests show that organisms even as small as sperm and viruses like HIV cannot pass through it.

Latex condoms [Bold] for men, if used correctly with every act of vaginal intercourse, are highly effective at preventing pregnancy, as well as STDs, including AIDS (HIV infection).

CDRH/FDA: 10/25/94

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

Mr. William D. Potter
Group Scientific Affairs Director
London International Group, plc
35 New Bridge Street
London EC4V 6BJ

Re: K922688
Durex Avanti™ Polyurethane Condom
Dated: November 24, 1997
Received: December 2, 1997

Dear Mr. Potter:

We have received the information in your letter dated November 24, 1997, regarding the 510(k) notification K922688 previously submitted for the device referenced above. However, as you informed us by telephone, subsequent to the submission of your letter, London International Group plans to continue product development of the Avanti™ condom and will leave the current labeling unchanged, i.e., for latex sensitive users only.

Notwithstanding your decision to continue marketing the Avanti™ condom per the original labeling limitations (enclosure), any future labeling change, such as the recent proposal in your November 24, 1997, letter, would need to be reviewed by the Food and Drug Administration (FDA). Such a labeling revision to remove the original labeling restrictions (latex sensitive users only) and target a general population will significantly change the device labeling and intended use of your condom (see 21 CFR 807.81(a)(3)).

If you intend to make such labeling changes at some point in the future, you will need to submit a new 510(k) and receive FDA clearance prior to marketing the Avanti™ condom with the new labeling. This 510(k) should also contain full reports and analyses from the two contraceptive efficacy studies of the Avanti™ condom, as well as reports from all slippage and breakage studies. Your analyses should fully compare the Avanti™ condom to latex condoms now available on the market, and these should support your proposed labeling changes.

Your letter referenced above will be added to the original 510(k) file with a copy of this letter. If you have any questions, please contact Mr. Colin M. Pollard at (301) 594-1180 or the Division of Small Manufacturers Assistance at (800) 638-2041 or (301) 443-6597.

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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

Records processed under FOIA Request # 2005-1976, Released by CDRH on 09-03-2015

DEPARTMENT OF HEALTH & HUMAN SERVICES

cc: HFZ-401
HFZ-470

JMK-C:\FILES\Condom\K922688 LIG Labeling New 510(k)
Revised:
3/11/98 - JMK/CMP
3/12/98 - JMK/LLY
3/16/98 - CMP
FINAL:CMP:JMK:lrm:3/16/98

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
Z470	Kennedy	3/12	Z470	Lilly	3/17/98			
Z470	Rolland	3/12/98						
Z470	Gaffney	3/17/98						

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

4

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-08-2015

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food And Drug Administration

reviewed by JMK 5/14/95

Memorandum

Date: 12/3/97

From: Document Mail Center (HFZ-401)

Subject: Premarket Notification Number(s): K922688/A8

To: Division Director: OB/DRAER

The attached information has been received by the 510(k) Document Mail Center (DMC), on the above referenced 510(k) submission(s). Since a final decision has been rendered, this record is officially closed.

Please review the attached document and return it to the DMC, with one of the statements checked below. Feel free to note any additional comments below.

Thank you for your cooperation.

_____Information does not change status of the 510(k); no other action required by the DMC; please add to the image file. [THE DIVISION SHOULD PREPARE A CONFIRMATION LETTER - AN EXAMPLE IS AVAILABLE ON THE LAN (K25). THIS DOES NOT APPLY TO TRANSFER OF OWNERSHIP. PLEASE BRING ANY TRANSFER OF OWNERSHIP TO POS.]

✓ Additional information requires a new 510(k) however the information submitted is incomplete. Notify the company to submit a new 510(k). [THE DIVISION SHOULD PREPARE THE (K30) LETTER ON THE LAN.]

_____Additional information requires a new 510(k); please process. [THIS INFORMATION WILL BE MADE INTO A NEW 510(k)].

_____No response necessary (e.g., hard copy of fax for the truthful and accuracy statement or 510(k) statement).

This information should be returned to the DMC within 10 working days from the date of this memorandum.

Reviewed by: J. Michael Kuczinski

Date: 3/12/98

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

Records processed under FOIA Request # 2[illegible]-1976; Released by CDRH on 09-03-2015

K922688/A8

9011
44

London International Group plc

35 New Bridge Street, London EC4V 6BJ. Telephone: 0171-489 1977 Direct Line: 0171-716 6295 Fax: 0171-329 4268

CONFIDENTIAL

W. D. Potter
Group Scientific Affairs Director

01223
423 232

RECEIVED
DEC 2 1 08 PM '97
FDA/CDRH/ODE/DMC

Dr L Yin, Ph.D.
Director, DRAERD
Food & Drug Administration
HFZ-470
9200 Corporate Boulevard
Rockville
MD 20850

By Fax: 001 301 480 4224 (and post)

cc: C Pollard, FDA

24 November 1997

Dear Lillian

Re: <u>510(K) Application</u>
<u>K922688</u>

Following our telephone discussion on 14 November 1997 I have now revised the statement that will appear on the back panel of the Avanti pack to reflect the higher breakage rate observed in clinical studies with Avanti. The original pack copy submitted to you contained the following statement

> When properly used, *Durex Avanti* condoms help protect against unwanted pregnancies and catching or spreading many sexually transmitted diseases (STDs) such as syphilis, gonorrhoea, chlamydial infections, genital herpes and AIDs. However, they cannot eliminate the risk. No method of contraception can provide 100% protection against pregnancy or the transmission of HIV(AIDs) and STDs. See information leaflet inside.

SK-43

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

8

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

We propose to amend this as follows:

> When properly used, *Durex Avanti* condoms help protect against unwanted pregnancies and catching or spreading many sexually transmitted diseases (STDs) such as syphilis, gonorrhoea, chlamydial infections, genital herpes and AIDs. However, they cannot eliminate the risk. In clinical studies, *Durex Avanti* has been shown to have slightly higher breakage rates than *Durex Ramses* latex condoms but well within the range of breakage rates published for regular latex condoms. No method of contraception can provide 100% protection against pregnancy or the transmission of HIV(AIDs) and STDs. See information leaflet inside.

In addition, we propose to revise the table that will be included in the information leaflet to bring the contraceptive efficacy rates for the different contraceptive methods in line with those in the document that you recently circulated (FDA 5/13/97). The revised table will be as follows:

	Pregnancies/100 Women Years	
	Typical Use	Lowest Expected
Durex® Avanti® Condom	10.1*	6.2*
Durex®Ramses®Sensitol® (Latex) Condoms	12.5*	2.3*
Published result for Regular Latex Condom	14	3
Polyurethane Female Condom	21	5
Vaginal Sponge *(no previous births)*	20	9
Vaginal Sponge *(previous births)*	40	20
Spermicide Alone	26	6
Natural Family Planning	25	1-9
No Method	85	-

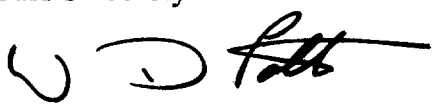
*LIG estimate - to be agreed with LARFPC

A copy of the report on the Health Decisions study has been forwarded to you separately.

My colleagues and I look forward to the opportunity of discussing these revisions to the proposed labelling via a conference call as soon as you have had a chance to review them.

Best Wishes

Yours sincerely



W D Potter

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

Records processed under FOIA Request # 2015-1896; Released by CDRH on 08-03-2015

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY - 4 1995

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Alice A. DePaul
Vice President
Apex Medical Technologies, Inc.
10064 Mesa Ridge Court
Suite 202
San Diego, California 92121

Re: K922688/E
Avanti™ Thin Polyurethane Condom
Dated: March 6, 1995
Received: March 7, 1995
Regulatory class: II
21 CFR §884.5300/Procode: 85 MOL

Dear Ms. DePaul:

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 or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug and Cosmetic Act (Act). You may therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the 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 may have under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described in your 510(k) premarket notification. An FDA finding of substantial equivalence of your device to a legally marketed predicate 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 any way represent your device or its labeling as being approved by FDA. If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), promotion, or advertising please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-302) at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose, and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

510(K) ROUTE SLIP

510(k) NUMBER K922688 PANEL OB DIVISION DRAER BRANCH OBDB

TRADE NAME "EXTRA PROTECTION" POLYURETHANE CONDOM

COMMON NAME

PRODUCT CODE

APPLICANT APEX MEDICAL TECHNOLOGIES, INC.
SHORT NAME APEXMEDITECH
CONTACT ALICE A DEPAUL
DIVISION
ADDRESS 10064 MESA RIDGE CT.,
SUITE #202
SAN DIEGO, CA 92121
PHONE NO. (___) ___-____ FAX NO. (___) ___-____

MANUFACTURER SCHMID LABORATORIES REGISTRATION NO. 1045600

DATE ON SUBMISSION 29-MAY-92 DATE DUE TO 510(K) STAFF

DATE RECEIVED IN ODE 04-JUN-92 DATE DECISION DUE 06-JUL-93

DECISION DECISION DATE

SUPPLEMENTS	SUBMITTED	RECEIVED	DUE POS	DUE	OUT
S001	06-APR-93	07-APR-93	06-JUL-93	04-MAR-94	
S002	19-APR-94	21-APR-94	05-JUL-94	20-JUL-94	01-AUG-94
S003	02-AUG-94	03-AUG-94	17-OCT-94	01-NOV-94	12-AUG-94
S004	01-SEP-94	02-SEP-94	16-NOV-94	01-DEC-94	30-JAN-95
S005	06-MAR-95	07-MAR-95	21-MAY-95	05-JUN-95	

CORRESPONDENCE	SENT	DUE BACK	
C005	30-JAN-95	01-MAR-95	HOLD LETTER
C001	03-SEP-92	02-JAN-93	HOLD LETTER
C002	04-MAR-94	03-APR-94	HOLD LETTER
C003	01-AUG-94	31-AUG-94	HOLD LETTER
C004	12-AUG-94	11-SEP-94	HOLD LETTER

OTHER SUBMISSIONS	SUBMITTED	RECEIVED	DUE POS	DUE	OUT

2

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Memorandum

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

Subject 510(k) NUMBER K922688/S5

To THE RECORD -- It is my recommendation that the subject 510(k) Notification:

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

Is this device subject to Postmarket Surveillance? [ ] YES [x] NO

Is this device subject to the Tracking Regulation? [ ] YES [x] NO

Was clinical data necessary to support the review of this 510(k)? [x] YES [ ] NO

This 510(k) contains: Truthful and Accurate Statement [ ] Requested [ ] Enclosed N/A
(required for originals received 3-14-95 and after)

- [x] A 510(k) summary OR [ ] A 510(k) statement
- [ ] The required certification and summary for class III devices

The submitter requests under 21 CFR 807.95: [ ] ~~No Confidentiality~~
[ ] Confidentiality for 90 days [ ] Continued Confidentiality exceeding 90 days

Predicate Product Code with panel and class: 85 MDL 8884.5300 Class II

Additional Product Code(s) with panel (optional):

REVIEW: Colin M. Pollard (BRANCH CHIEF) OGDB (BRANCH CODE) 5/3/95 (DATE)

Rnathing 5/3/95

NAL REVIEW: [signature] (DIVISION DIRECTOR) 5/3/95 (DATE)

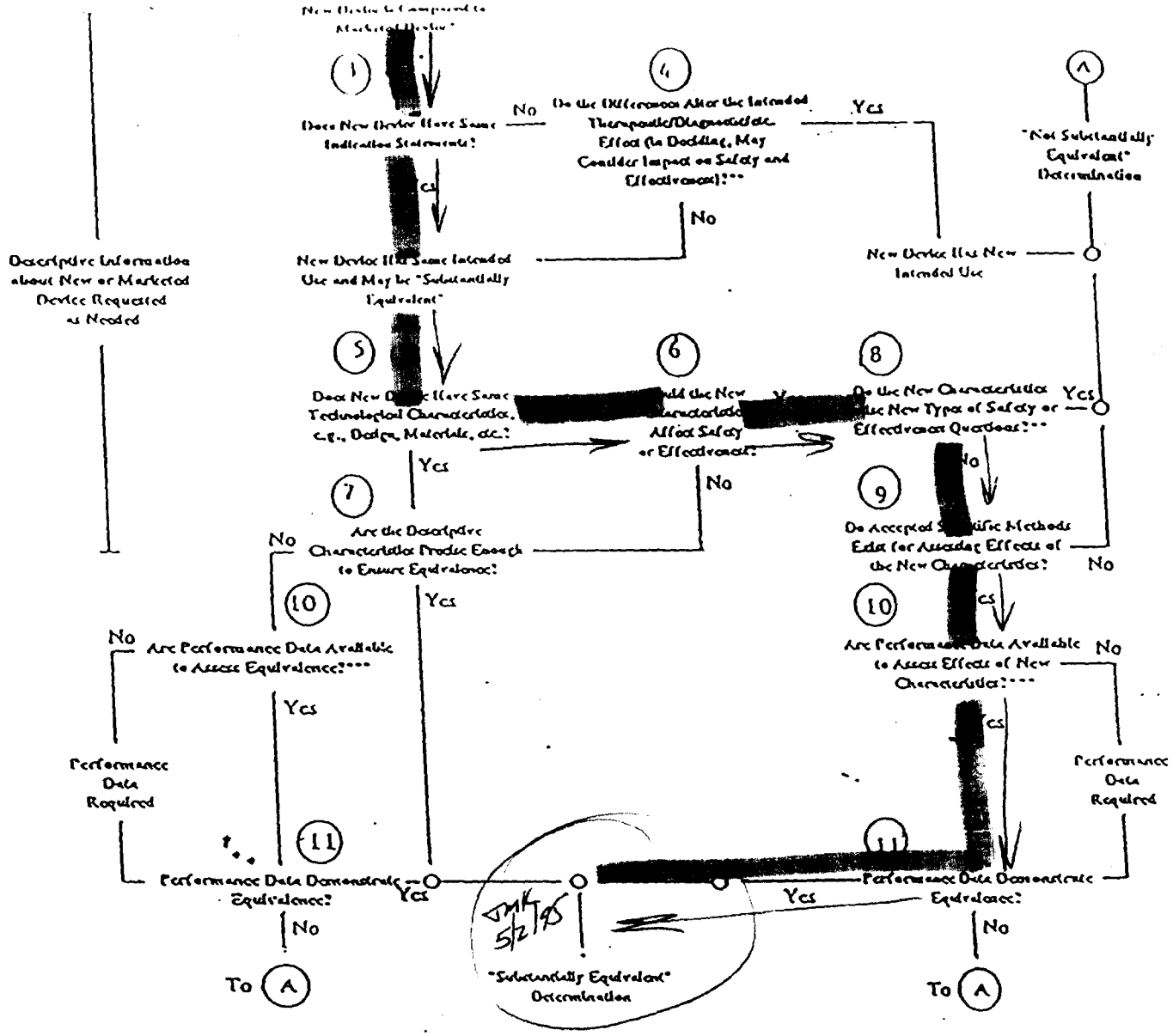
Revised 3/8/95

3

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

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.

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

I N T E R O F F I C E M E M O R A N D U M

Date: 01-May-1995 09:27am EDT
From: Walter A. Goetz
WAG
Dept: OIS-IOIS
Tel No: 594-4550

TO: John M. Kuchinski (JMK)

CC: Colin M. Pollard (CMP)
CC: Jennifer Rohr (JLR)
CC: Mridulika Virmani (MSV)

Subject: RE: New ProCode for New Material Condom

As requested, I have issued the following new Product Code:

85MOL Condom, Non-Latex Class II Reg. 884.5300

If you have any questions, please get in touch with me.

Walt

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION-MAKING DOCUMENTATION

K922688/E

Trade Name: Avanti™ Thin Condom - (This is a change in the device Trade Name)

Applicant: Apex Medical Technologies, Inc.
10064 Mesa Ridge Court
San Diego, California 92121

Contact: Ms. Alice DePaul
(619) 535-0012

NARRATIVE DEVICE DESCRIPTION

1. Intended Use:

The Avanti™ Thin condom is intended for contraception and as a prophylactic for the prevention of sexually transmitted disease (STDs). An appropriate statement of the intended use (contraceptive and prophylaxis) is located on the back panel of the packaging. As amended the device conforms to our interim labeling presented to the industry by letter, dated November 21, 1994.

2. Device Description:

The Avanti™ Thin condom is a polyurethane rubber condom. The Avanti™ Thin condom is made of Estane supplied by B.F. Goodrich (block copolymer - polystyrene and polybutadiene). The process is a solvent (tetrahydrofuran) dipped process.

	YES	NO
Is the device life-supporting or life sustaining?		✓
Is the device implanted (short-term or long-term)?		✓
Does the device design use software?		✓
Is the device sterile?		✓
Is the device for single use?	✓	
Is the device for home use?	✓	
Is the device for prescription use?		✓
Does the device contain a drug or biological product as a component?		✓
Is this device a kit?		✓

Apex Medical Technologies, Inc., has provided labeling for the Avanti™ Thin condom, dated April 17, 1995, that satisfies our concerns for interim labeling required for new material condoms. (NOTE: The name of the device has been changed to indicate specific trade name.)

6

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

The following serves to highlight and summarize the testing performed on this device to support a substantial equivalence determination.

Clinical Performance - Contraceptive Effectiveness

A clinical protocol to investigate the contraceptive effectiveness in a prospective clinical study has been approved by letter dated May 4, 1994.

Labeling

The labeling for the Avanti™ Thin condom has been resolved. (See Letter dated April 17, 1995, from Mr. McGolthlin.) The company has provided labeling, pursuant to and in line with our November 21, 1994, notification.

As background, the Center has determined that the labeling must reflect that the intended use for the device is limited to latex sensitive persons. Further, the labeling should indicate that the contraceptive effectiveness has not been determined, and that clinical trials to determine effectiveness are underway. This issue has been addressed by Apex Medical Technologies and the proposed labeling conforms with our November 21, 1994, letter and interim labeling.

Slippage and Breakage

The study submitted by Apex and used to support that their breakage and slippage rate (for the Avanti™ condoms) is equivalent to the latex control has been determined to be acceptable.

Shelf Life

The application included information to support a 3 year shelf life for the Avanti™ Thin Condom. Mr. Don Marlowe has reviewed the data submitted to support the tentative 3 year shelf life and stated there is no substantial change in the material caused by exposures of up to one year at temperatures up to 40°C. The company will adhere to a test program to verify the long term shelf life of the Avanti™ Thin Condom.

Viral Penetration (Barrier Properties)

Based on viral penetrations studies the worst case leak in a Avanti™ Condom led to a calculated hole size of 5μ, corrected for loss of virus challenge titer. The adjusted calculated hole size is comparable the a latex condom.

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

Chemistry

The Avanti™ condom is manufactured using a thermoplastic polyurethane, Estane 5767 supplied by B.F. Goodrich. Pellets of the polyurethane are dissolved in tetrahydrofuran (subsequently evaporates) and the condom is dipped onto mandrels. The application contains information on the level of THF in the finished device. Dr. Tsai has reviewed this material and identified that the identified levels are acceptable.

Toxicology/Biocompatibility

The sponsor has conducted adequate biocompatibility tests on Avanti™ Condom and that the results of the testing show that the material is relatively safe for its intended use.

Quality Assurance

100% electronic hole detection is conducted using the previously validated Uson Corporation's Model 100, vacuum decay leak tester. The applicant has also conducted testing to validate this test unit (K871358, image p 38) that was accepted as an in-process detection system.

Quality Control Release Procedures

The quality control release testing is in accordance with Mil Std 105E, with water leak testing equivalent to ASTM D3492-89 at Level I, Normal, 0.4 AQL. Physical testing (tensile strength and elongation) at Level S-2, 2.5 AQL.

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

		YES	NO	
1.	IS PRODUCT A DEVICE?	✓		IF NO, STOP
2.	DEVICE SUBJECT TO 510(k)?	✓		IF NO, STOP
3.	SAME INDICATION STATEMENT?	✓		IF YES, GOTO 5
4.	DO DIFFERENCES ALTER THE EFFECT OR RAISE NEW ISSUES OF SAFETY OR EFFECTIVENESS?			IF YES,STOP->NSE
5.	SAME TECHNOLOGICAL CHARACTERISTICS?		✓	IF YES, GOTO 7
6.	COULD THE NEW CHARACTERISTICS AFFECT SAFETY OR EFFECTIVENESS?	✓		IF YES, GOTO 8
7.	DESCRIPTIVE CHARACTERISTICS PRECISE ENOUGH?			
8.	NEW TYPES OF SAFETY AND EFFECTIVENESS QUESTIONS?		✓	IF YES, STOP->NSE
9.	ACCEPTED SCIENTIFIC METHODS EXIST?	✓		IF NO,STOP->NSE
10.	PERFORMANCE DATA AVAILABLE?	✓		IF NO,REQ. DATA
11.	DATA DEMONSTRATE EQUIVALENCE	✓		IF YES, STOP->SE

* "yes" responses to 4, 6, 8, and 11, and every "no" response requires an explanation below

Response to Question 5, 6, 8 and 11

5. SAME TECHNOLOGICAL CHARACTERISTICS?

This device does not have the same technological characteristics as a latex condom. The device material is a polyurethane material and as described above, and not natural latex rubber. As such the device does not exhibit many of the same sensitization problems as

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

a latex condom and would, therefore, be acceptable for use by latex sensitive persons.

6. COULD THE NEW CHARACTERISTICS AFFECT SAFETY OR EFFECTIVENESS?

The new technological characteristics may affect the safety or effectiveness of this device when used as a contraceptive or as a prophylactic. Issues regarding the material property differences may compromise this device as a barrier or may affect its effectiveness in use.

8. NEW TYPES OF SAFETY AND EFFECTIVENESS QUESTIONS?

The questions raised above are not new questions of safety or effectiveness. Similar questions may arise for latex condom if there were significant changes in the device dimensions.

11. DATA DEMONSTRATE EQUIVALENCE

Significant issues regarding device testing have been addressed including the ability of the material to be a barrier to virus penetration, in-use slippage and breakage, material shelf life, toxicity of the material, etc.

The contraceptive effectiveness of this device is to be determined in a prospective, randomized clinical trial that has been approved under IDE G940041.

Recommendation:

The Avanti™ Thin Condom is substantially equivalent to the generic class latex condom.

ProCode: 85 ~~HIS~~ MOL JMK 4/24/95
Class: II
CFR #: 21 CFR § 884.5300

J. Michael Kuchinski Date: 4/24/95
Microbiologist (HFZ-470)
B:\K922688E.RE1

Colin M. Pollard 4/26/95
Chief, Ob/Gyn Branch Date:

/✓/ Concur

/ / Do Not Concur

Comments: This is the 2nd AVANTI™ polyurethane condom we have cleared. The first (Avanti SuperThin) is already on the market per the same labeling restrictions. CMP 4/26/95

10

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

I N T E R O F F I C E M E M O R A N D U M

Date: 21-Apr-1995 05:09pm EDT
From: John J. Farnham
JJF
Dept: OC-DE2
Tel No: 594-4616

TO: John M. Kuchinski (JMK)

CC: Tim R. Wells (TRW)

Subject: Avanti "Thick" polyurethane

Mike,

Called back but you weret't there. Hope this is what you need.

TRADENAME IS ACTUALLY "THIN", COMPARED TO THE "SUPERTHIN" THAT IS ALREADY ON THE MARKET.

CMP 5/3/95

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

ave reviewed the facsimile copy of the firm's April 17, 5, submission (K922688/A5). Provided that the statement "For Latex Sensitive Individuals" is present on the front panel (not legible in my copy), the package labeling contained in K922688 appears to be in conformance with the acceptable wording for non-latex condoms as described in the November 1994 letter to industry.

The instructions for use also appear to be adequate, although OC defers to the ODE evaluation. If you need any further concurrence please contact me on Monday, April 24, in the morning.

John Farnham

12

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

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*****************************************************************************
*****************************************************************************
        CCCCCCCC          DDDDDDDD          RRRRRRRR          HH    HH
        CC                DD      D         RR      R         HH    HH
        CC                DD      D         RRRRRRRR          HHHHHHHH
        CC                DD      D         RR    RR          HH    HH
        CCCCCCCC          DDDDDDDD          RR     RR         HH    HH
*****************************************************************************
*****************************************************************************
```

****

ALL-IN-1 USER: JMK

****

MAIL TO HFZ-470, ATTN: KUCHINSKI, J. MICHAEL, ODE, CORP

```
*****************************************************************************
*****************************************************************************
                                  04/24/95
                                  10:31am
   ***************                                   ***************
                              HAVE A HAPPY DAY!
*****************************************************************************
*****************************************************************************
```

13

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

K9226888 /A 5

APEX MEDICAL TECHNOLOGIES, INC.
10064 Mesa Ridge Ct. • Suite #202
San Diego, CA 92121
(619) 535-0012 • FAX (619) 535-9715

RECEIVED
18 APR 95 08 56
FDA/CDRH/ODE/DHC

April 17, 1995

Michael Kuchinski
Food and Drug Administration
Bureau of Medical Devices
Document Control Center (HFZ - 401)
9200 Corporate Blvd.
Rockville, MD 20850

Re: K9226888
Avanti TM "Thick Condom"

Dear Mr Kuchinski:

This letter is in response to our telephone conversaton of February 14, 1995. During this discussion, issues related to labeling were discussed.

Your specific requests for labeling changes included:

(b) (4)

[redacted]

14

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

(b) (4)

[redacted]

In compliance with these requests, attached to this letter is revised draft labeling which we believe addresses all of the issues raised in our telephone conversation. Also, as stated in our last letter to you, the final printed carton will be submitted to FDA prior to the product's introduction into the marketplace.

We consider our intent to market this thicker polyurethane condom confidential commercial information, and request that this information be considered as such by the FDA. Additionally, some details contained in this letter are confidential in nature. We request the removal of the proprietary details of this submission from any potential disclosure under the Freedom of Information Act.

Should you require additional information, please contact me at (619) 535-0203.

Sincerely,

Mark W. McGlothlin
President

15

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

Condom Foil Labeling:

Front of foil:

Avanti Thin™

1 Duron™ Condom

Back of Foil:

Not to be sold without additonal important consumer information

Lubricated

Distributed by Schmid Laboratories
Div. Of London Int'l U.S. Holdings, Inc.
Sarasota, FL 34230-4703

LOT #

16

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

STORAGE

1. Store condoms in a cool, dry place.

FOIL PACKAGE

2. The condom should not be removed from the foil pack until ready for use.

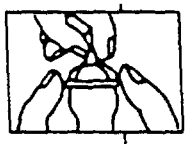
3. Tear open the end of the foil package carefully to remove condom. Rough handling, jewelry or fingernails can damage the condom and reduce its effectiveness.

USING THE CONDOM

4. To further reduce the chance of spreading or acquiring a sexually transmitted disease, immediately wash the hands, penis and surrounding area, and external vaginal area before and after sexual contact.

5. Do not use condom if foil package is damaged or open or if the condom material is sticky or brittle or obviously damaged.

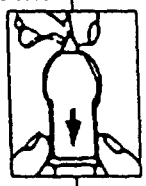
6. Place a new condom on the penis each time prior to any foreplay, genital contact or penetration to avoid contact with any body fluid that may contain STD organisms.



7. Do not unroll the condom before putting it on as this may damage the condom and make it more difficult to use properly.

8. Put the condom over the head of the erect penis. Leave about 1/2" space at the end. Some condoms have small receptacle ends which provide the required space to collect semen. Squeeze end slightly to release air to avoid an air pocket.

9. Slowly unroll all the way to the base of the penis while still squeezing end of condom. If the condom does not unroll to the base of the penis, it has been put on incorrectly and should be discarded.



10. If a lubricant is desired, AVANTI™ condoms are safe for use with both water-based and oil-based lubricants.

11. 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 quickly 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.

12. If the condom breaks, or if for any reason, semen spills or leaks out during use, it is advisable that both partners should cleanse themselves wherever contact may have occurred, as soon as possible.

13. Remember—never reuse a condom.

PRECAUTIONS

14. If there are lesions, open sores, viral warts or other abnormalities noticeable on either party, it is recommended that you avoid sexual intercourse and consult a physician.

15. To avoid damage to furniture, do not place condom or open foil package on surface where lubricant can leak out.

Important Consumer Information:

You may use this polyurethane condom if you or your partner are allergic to latex.

You should know:

- **The risks of pregnancy and sexually transmitted diseases (STD's), including AIDS (HIV infection), are not known for this condom. A study is being done.**
- **There are laboratory tests on this polyurethane material. These tests show that organisms even as small as sperm and viruses like HIV cannot pass through it.**

Latex condoms for men, if used correctly with every act of vaginal intercourse, are highly effective at preventing pregnancy, as well as STDs, including AIDS (HIV infection).

17

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

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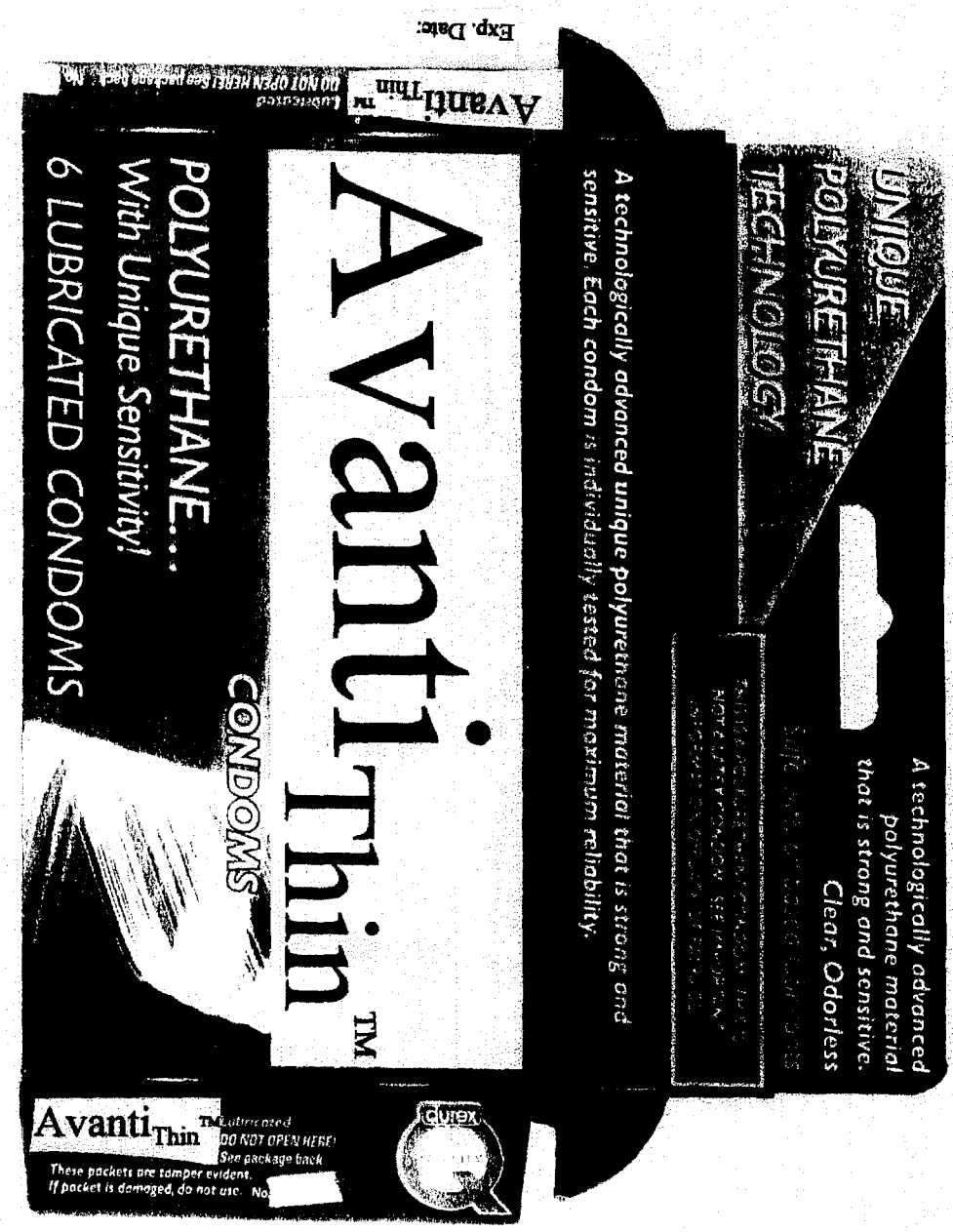

18

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

Directions for opening package:
Press along perforation. Remove top panel and discard. Package can be easily reclosed. (Patent No. 4,291,807)

No.

Instructions printed inside.
Instrucciones en Español impresas adentro.

Important Consumer Information:

You may use this polyurethane condom if you or your partner are allergic to latex.
You should know:

- **The risks of pregnancy and sexually transmitted diseases (STD's), including AIDS (HIV infection), are not known for this condom. A study is being done.**
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Latex condoms for men, if used correctly with every act of vaginal intercourse, are highly effective at preventing pregnancy, as well as STDs, including AIDS (HIV infection).

Storage: Avoid prolonged storage of condoms at temperatures in excess of 100 degrees Fahrenheit– storage for short periods of time at this temperature will not be harmful to the product. Avoid any storage close to a hot radiator, hot air duct or similar object. Any use of condoms for other than vaginal intercourse can increase the potential of damage to the condom.

For maximum benefits, it is important to follow the instructions printed on the inside of the carton. 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 STD's. Therefore, the condom should be applied each and every time before such contact occurs.

Distributed by London International U.S. Holdings, Inc.
Schmid Laboratories Division, Sarasota, FL 34230-4703
Duron®, a trademark for a unique polyurethane film.

U.S. Patent No.'s 4,855,169;4,954,309;5,129,256

(UPC CODE)

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

FAX TRANSMISSION

APEX MEDICAL TECHNOLOGIES, INC.
10064 MESA RIDGE COURT, SUITE 202
SAN DIEGO, CA 92121
(619) 535-0203
FAX: (619) 535-9715

To:	Michael Kuchinski	**Date:**	April 17, 1995
Fax #:	1-301-594-2339	**Pages:**	7, including this cover sheet.
From:	Mark W. McGlothlin		
Subject:	Document Delivery Information		

COMMENTS:

Per our telephone conversation today, the attached document is being sent out by priority Federal Express letter today. It will have Federal Express air bill number 2814710990. Please call if you have any difficulties in receiving this information tomorrow.

Mark McGlothlin

20

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

10064 Mesa Ridge Ct. • Suite #202
San Diego, CA 92121
(619) 535-0012 • FAX (619) 535-9715

April 17, 1995

Michael Kuchinski
Food and Drug Administration
Bureau of Medical Devices
Document Control Center (HFZ - 401)
9200 Corporate Blvd.
Rockville, MD 20850

Re: K9226888
Avanti TM "Thick Condom"

Dear Mr Kuchinski:

This letter is in response to our telephone conversaton of February 14, 1995. During this discussion, issues related to labeling were discussed.

Your specific requests for labeling changes included:

(b) (4)

[redacted]

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

(b) (4)

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Should you require additional information, please contact me at (619) 535-0203.

Sincerely,

Mark W. McGlothlin
President

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Avanti Thin™

1 Duron™ Condom

Back of Foil:

Not to be sold without additonal important consumer information

Lubricated

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Div. Of London Int'l U.S. Holdings, Inc.
Sarasota, FL 34230-4703

LOT #

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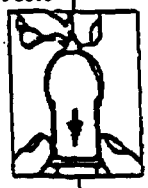

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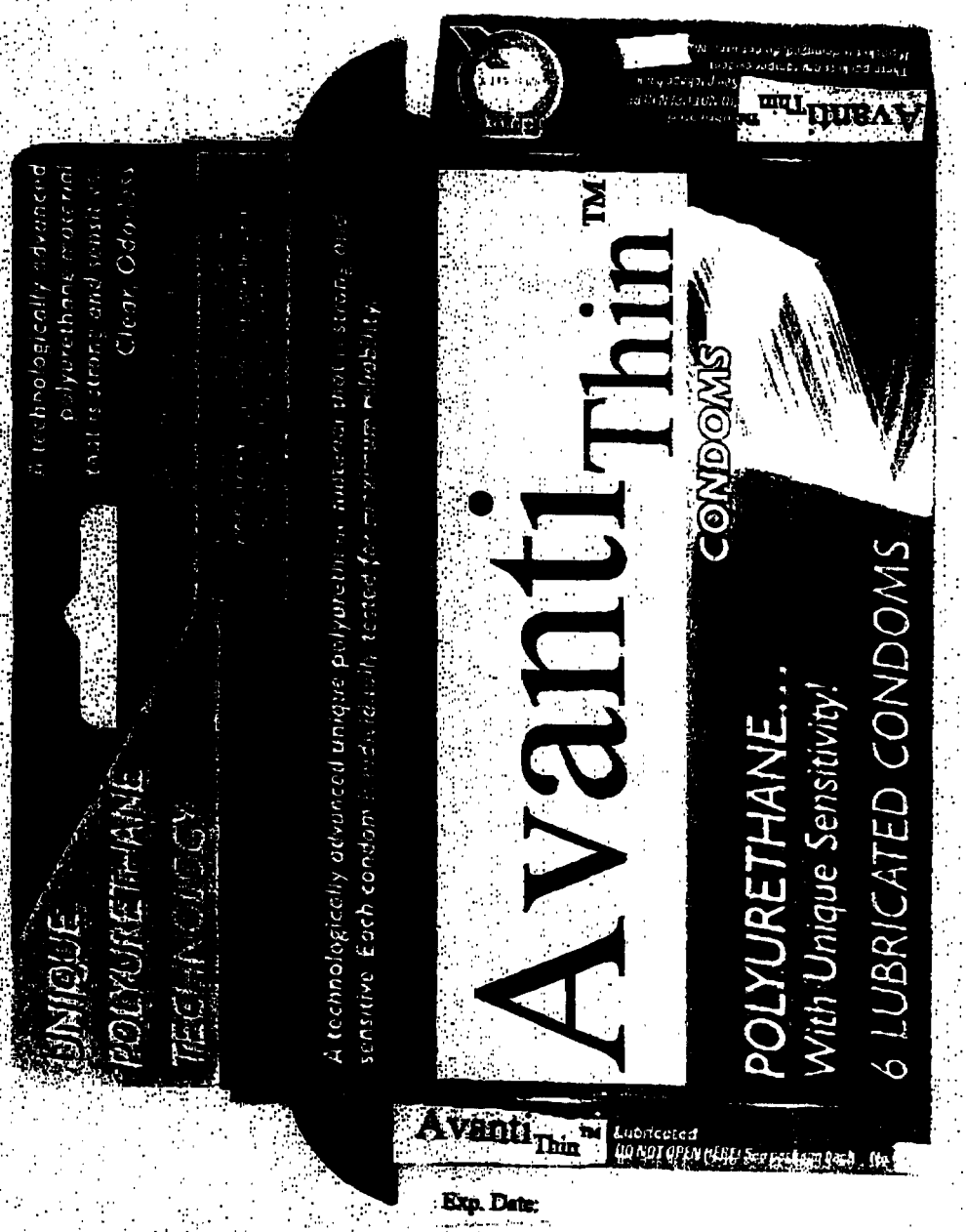
24

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015



25

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

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Distributed by London International U.S. Holdings, Inc.
Schmid Laboratories Division, Sarasota, FL 34239-4703
Durex®, a trademark for a unique polyurethane film.

U.S. Patent No.'s 4,855,169;4,954,309;5,129,256

[redacted] (UPC CODE) [redacted]

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

I N T E R O F F I C E M E M O R A N D U M

Date: 02-Feb-1995 10:26am EST
From: Donald E. Marlowe
DEM
Dept: OST-DMMS
Tel No: 443-7003

TO: John M. Kuchinski (JMK)

Subject: K 9226888

I **have reviewed the data supplied in the letter** from Alice DePaul, Apex Medical Technologies Inc., to Michael Kuchinski, FDA/BMD, dated January 30, 1995. The focus of my review was the data to support the desire of the firm to have a 3 year shelf life/expiration date on their "thick condom".

This data shows that there is no substantial change in the material caused by exposures of up to one year at temperatures up to 40 C. It also shows no degradation in the material during an accelerated ageing test of exposure of 70 C for 7 days.

ecommend that the 3 year shelf life is appropriate, based on the data plied.

Donald E. Marlowe

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

DIVISION OF REPRODUCTIVE, ABDOMINAL, EAR, NOSE AND THROAT
AND RADIOLOGICAL DEVICES

MEMORANDUM OF TELEPHONE CONVERSATION

BETWEEN: J. Michael Kuchinski Date: 2/14/95, 4/10/95 and 4/11/95

AND: Mark W. McGlothlin

TITLE: President

COMPANY: Apex Medical Technologies, Inc.

PHONE NUMBER: (619) 535-0203

FAX NUMBER: (619) 535-9715
(if applicable)

DOCUMENT NUMBER: K922688/E
(if applicable)

SUMMARY: I telephoned Mr. McGlothlin initially on January 13, 1995 to discuss a need for additional information (see letter dated January 30, 1995). A FAX received January 30, 1995 was the result of that initial conversation. At issue was a need for shelf life information (data and shelf life date) and final labeling per our November 21, 1994, letter to industry. The formal response to our January letter and follow-up telephone calls has been submitted by cover dated March 6, 1995.

On February 14, 1995, I telephoned Mr. McGlothlin about the labeling submitted as follows:

(b) (4)

[redacted]

In follow-up on April 10 and 11, 1995, I telephoned Mr. McGlothlin to request that the revised labeling be sent As-Soon-As-Possible. He indicated that London International needed to resolve the language for presentation. He stated that revised labeling would be submitted by Monday April 17.

Signed: JM.K

Original to: K922688.TEL
Copy to: Chron

SLJ/RRG 11/20/92 Rev. 3/30/94

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

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)
9200 Corporate Blvd.
Rockville, Maryland 20850

March 09, 1995

APEX MEDICAL TECHNOLOGIES, INC.
10064 MESA RIDGE CT.,
SUITE #202
SAN DIEGO, CA 92121
ATTN: ALICE A. DEPAUL

510(k) Number: K922688
Product: "EXTRA PROTECTION" POLYURETHANE CONDOM

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. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

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

29

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

K922688 / S5

RECEI
MAR 95
FDA/CDRH/ODE/DMC

APEX MEDICAL TECHNOLOGIES, INC.

10064 Mesa Ridge Ct. • Suite #202
San Diego, CA 92121
(619) 535-0012 • FAX (619) 535-9715

March 6, 1995

Michael Kuchinski
Food and Drug Administration
Bureau of Medical Devices
Document Control Center (HFZ - 401)
9200 Corporate Blvd.
Rockville, MD 20850

Re: K9226888 Avanti TM "Thick Condom"

Dear Mr Kuchinski:

This letter is in response to your January 13, 1995 phone call with me, and the follow-up letter from Colin Pollard dated January 30, 1995 (received at Apex on February 13, 1995), and to your phone call to me on February 14, 1995. With respect to the January 13, 1995 phone call, and Colin Pollard's letter dated January 30, 1995, a facsimile from Apex Medical Technologies, Inc., dated January 30, 1995 was sent to your attention addressing all of the issues raised by yourself and by Colin Pollard. Enclosed with this letter is an original signed copy of the January 30, 1995 facsimile letter which formally documents this response. On February 14, 1995, you discussed the contents of our January 30, 1995 facsimile letter, and you raised additional issues. A response to these additional issues is still being prepared, and a formal response will be sent to you shortly.

We consider our intent to market this thicker polyurethane condom confidential commercial information, and request that this information be considered as such by the FDA. Additionally, some details contained in this letter are confidential in nature. We request the removal of the proprietary details of this submission from any potential disclosure under the Freedom of Information Act.

Should you require additional information, please contact me at (619) 535-0203.

Sincerely,

Mark W. McGlothlin
President

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

APEX MEDICAL TECHNOLOGIES, INC.

10064 Mesa Ridge Ct. • Suite #202
San Diego, CA 92121
(619) 535-0012 • FAX (619) 535-9715

January 30, 1995

Michael Kuchinski
Food and Drug Administration
Bureau of Medical Devices
Document Control Center (HFZ - 401)
1390 Piccard Drive
Rockville, MD 20850

Facsimile Number: 1-301-594-2339 No. Pages: 13

Re: K9226888
Avanti TM "Thick Condom"

Dear Mr Kuchinski:

This letter is in response to your request for additional information regarding the above-referenced 510(k) submission. This letter contains the requested information, as follows:

(b) (4)

[redacted]

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

We consider our intent to market this thicker polyurethane condom confidential commercial information, and request that this information be considered as such by the FDA. Additionally, some details contained in this letter are confidential in nature. We request the removal of the proprietary details of this submission from any potential disclosure under the Freedom of Information Act.

Should you require additional information, please contact me at (619) 535-0165.

Sincerely,

Alice A. DePaul
Vice President

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

(b)(4) Test Data

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

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

(b)(4) Test Data

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

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

(b)(4) Test Data

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

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

(b)(4) Test Data

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

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

(b)(4) Test Data

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

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(b)(4) Test Data

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

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(b)(4) Test Data

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

OK

UNIQUE POLYURETHANE TECHNOLOGY

FOR LATEX SENSITIVE CONDOM USERS!

A technologically advanced polyurethane material that is strong and sensitive.
Clear, Odorless
Safe with oil based lubricants

THIS IS A POLYURETHANE CONDOM. THIS IS NOT A LATEX CONDOM. SEE IMPORTANT INFORMATION ON BACK OF PACKAGE.

OK for content should be larger

OK

A technologically advanced unique polyurethane material that is strong and sensitive. Each condom is individually tested for maximum reliability.

TRADEMARK

TRADEMARK

Lubricated
DO NOT OPEN HERE! See package back

Exp. Date:

CONDOMS

POLYURETHANE...
With Unique Sensitivity!
6 LUBRICATED CONDOMS

Lubricated
DO NOT OPEN HERE!
See package back

TRADEMARK

These packets are tamper evident.
If packet is damaged, do not use.

What will be the Trademark what claims... "Unique Sensitivity!"?
how will this be differentiated from the thin Avanti™

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

No.

Directions for opening package:
Press along perforation. Remove top panel and discard. Package can be easily reclosed. (Patent No. 4,291,807)

IMPORTANT CONSUMER INFORMATION

You should know:

- *You may use this polyurethane condom if you or your partner are allergic to latex.*
- *The risks of pregnancy and sexually transmitted diseases (STDs), including AIDS (HIV infection), are not known for this condom. A study is being done.*
- *There are laboratory tests on this polyurethane material. These tests show that organisms even as small as sperm and viruses like HIV cannot pass through it.*
- *Latex condoms for men, if used correctly with every act of vaginal intercourse, are highly effective at preventing pregnancy, as well as STDs, including AIDS (HIV infection).*

should be modified

Storage: Avoid prolonged storage of condoms at temperatures in excess of 100° Fahrenheit - storage for short periods of time at his temperature will not be harmful to the product. Storage in a cool dry place at room temperature is recommended. Avoid any storage close to a hot radiator, hot air duct or similar object. Any use of condoms for other than vaginal intercourse can increase the potential of damage to the condom.

For maximum benefits, it is important to follow the instructions printed on the inside of the carton. 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 STD's. Therefore, the condom should be applied each and every time before such contact occurs.

Distributed by London International U.S. Holdings, Inc.
Schmid Laboratories Division, Sarasota, FL 34230-4703

2nd Trademark ®, a trademark for a unique polyurethane film.

U.S. Patent No.'s 4,855,169; 4,954,309;5,129,256

UPC BAR CODE

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

STORAGE

1. Store condoms in a cool, dry place.

FOIL PACKAGE

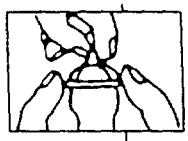
2. The condom should not be removed from the foil pack until ready for use.

3. Tear open the end of the foil package carefully to remove condom. Rough handling, jewelry or fingernails can damage the condom and reduce its effectiveness.

USING THE CONDOM

4. To further reduce the chance of spreading or acquiring a sexually transmitted disease, immediately wash the hands, penis and surrounding area, and external vaginal area before and after sexual contact.

5. Do not use condom if foil package is damaged or open or if the condom material is sticky or brittle or obviously damaged.

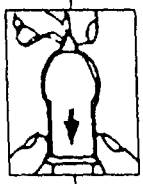


6. Place a new condom on the penis each time prior to any foreplay, genital contact or penetration to avoid contact with any body fluid that may contain STD organisms.

7. Do not unroll the condom before putting it on as this may damage the condom and make it more difficult to use properly.

8. Put the condom over the head of the erect penis. Leave about 1/2" space at the end. Some condoms have small receptacle ends which provide the required space to collect semen. Squeeze end slightly to release air to avoid an air pocket.

9. Slowly unroll all the way to the base of the penis while still squeezing end of condom. If the condom does not unroll to the base of the penis, it has been put on incorrectly and should be discarded.



10. If a lubricant is desired, TRADE-MARK condoms are safe for use with both water-based and oil-based lubricants.

11. 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 quickly 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.

12. If the condom breaks, or if for any reason, semen spills or leaks out during use, it is advisable that both partners should cleanse themselves wherever contact may have occurred, as soon as possible.

13. Remember—never reuse a condom.

PRECAUTIONS

14. If there are lesions, open sores, viral warts or other abnormalities noticeable on either party, it is recommended that you avoid sexual intercourse and consult a physician.

15. To avoid damage to furniture, do not place condom or open foil package on surface where lubricant can leak out.

Important Consumer Information:

You may use this polyurethane condom if you or your partner are allergic to latex.

You should know:

- **The risks of pregnancy and sexually transmitted diseases (STD's), including AIDS (HIV infection), are not known for this condom. A study is being done.**
- **There are laboratory tests on this polyurethane material. These tests show that organisms even as small as sperm and viruses like HIV cannot pass through it.**

Latex condoms for men, if used correctly with every act of vaginal intercourse, are highly effective at preventing pregnancy, as well as STDs, including AIDS (HIV infection).

6K

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

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Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

Condom Foil Labeling:

Front of foil:

TRADEMARK
1 2nd Trademark Condom

Back of Foil:

Add statement

Distributed by Schmid Laboratories
Div. Of London Int'l U.S. Holdings, Inc.
Sarasota, FL 34230-4703

LOT #

Lubricated

NOT TO BE SOLD WITHOUT IMPORTANT CONSUMER INFORMATION

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Alice A. DePaul
Vice President
Apex Medical Technologies, Inc.
10064 Mesa Ridge Court
Suite 202
San Diego, California 92121

JAN 30 1995

Re: K922688/D
Avanti™ "Thick Condom"
Dated: September 1, 1994
Received: September 2, 1994

Dear Ms. DePaul:

We have reviewed your Section 510(k) notification of intent to market the device referenced above. Even though you have responded to our letter of August 1, 1994, your response to question number 2 is not adequate. Therefore, 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 that you revise your device labeling to conform to our November 21, 1994, letter and Interim Labeling Requirements For Condoms Made From New Materials (copy enclosed). The language and format for both the principal display panel and the back panel of the retail package are specified in the interim labeling requirements. In addition, pursuant to a January 17, 1995, telephone conversation between Mr. Mark McGlothlin and Mr. J. Michael Kuchinski, your labeling should include a proposed shelf life, supported by suitable and acceptable *in vitro* data.

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

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(f) and (h), and you have received a letter from FDA allowing you to do so. 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 exemption (IDE) regulations.

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

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

If the 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 Mr. J. Michael Kuchinski at (301) 594-1180. 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 Colin M. Pollard
Chief, Obstetrics/Gynecology Devices Branch
Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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

45

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

Ms. Alice A. DePaul
Vice President
Apex Medical Technologies, Inc.
10064 Mesa Ridge Court
Suite 202
San Diego, California 92121

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Avanti™ "Thick Condom"
Dated: September 1, 1994
Received: September 2, 1994

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46

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

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Sincerely yours,

Colin M. Pollard
Chief, Obstetrics/Gynecology Devices Branch
Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ-470 Division
D.O.

B:\K922688D.AI:JMKuchinski:01/26/95
C:\Wp51\Files\510k\K922688D.AI
Final: 1/26/95:slj

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
Z-470	Kuchinski	1/26/95						
Z-470	Tillman for CMP	1/26/95						

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Memorandum

Date

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

Subject 510(k) NOTIFICATION K922688/S4

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. Information requested by phone 1/17 and 23/95 has not been provided by 1/26/95 COB.

_____ (D) Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Additional Comments: Additional information is necessary JMK 1/26/95

Is this device subject to Postmarket Surveillance? Yes ☐ No ☐

This 510(k) contains: (check appropriate box(es))

☐ A 510(k) summary of safety and effectiveness, or

☐ A 510(k) statement that safety and effectiveness information will be made available

☐ The required certification and summary for class III devices

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: for Dawn Lea Tillman (BRANCH CHIEF) | OGDB BRANCH CODE | 1/26/95 (DATE) (NIF)

FINAL REVIEW: _____ (DIVISION DIRECTOR) (DATE)

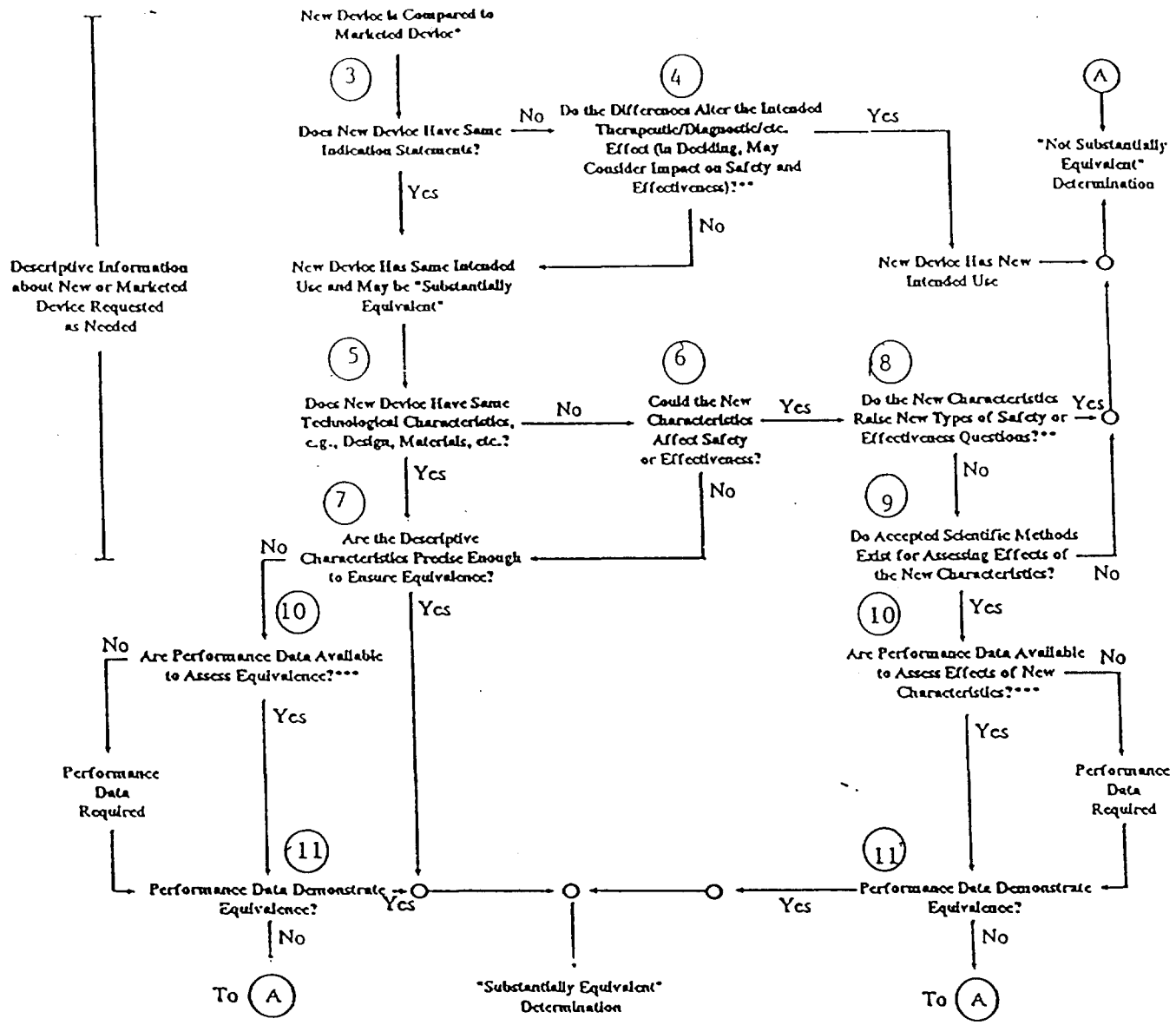
*DOES NOT APPLY TO ANY "SE" DECISIONS Revised 11/18/91

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

18

Records processed under FOIA 2015-2010 released by CDRH on 09-03-2015

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.

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

DIVISION OF REPRODUCTIVE, ABDOMINAL, EAR, NOSE AND THROAT AND RADIOLOGICAL DEVICES

MEMORANDUM OF TELEPHONE CONVERSATION

BETWEEN: J. Michael Kuchinski Date: January 17 and 23, 1995

AND: Mr. Mark McGlothlin

TITLE: President

COMPANY: Apex Medical Technologies, Inc.

PHONE NUMBER: (619) 535-0012

FAX NUMBER:
(if applicable)

DOCUMENT NUMBER: K922688/D
(if applicable)

(b) (4)

Signed: J. Michael Kuchinski

Original to: K922688/D

SO

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION-MAKING DOCUMENTATION

K922688/D

Trade Name: Avanti™ Thick Condom

Applicant: Apex Medical Technologies, Inc.
10064 Mesa Ridge Court
San Diego, California 92121

Contact: Ms. Alice DePaul
(619) 535-0012

NARRATIVE DEVICE DESCRIPTION

1. Intended Use:

The Avanti™ Thick condom is intended for contraception and as a prophylactic for the prevention of sexually transmitted disease (STDs). An appropriate statement of the intended use (contraceptive and prophylaxis) is located on the back panel of the packaging. As amended the device conforms to our interim labeling presented to the industry by letter, dated November 21, 1994.

2. Device Description:

The Avanit™ Condom is a polyurethane rubber condom. The Avanti™ condom is made of Estane supplied by B.F. Goodrich. The process is a solvent (tetrahydrofuran) dipped process.

	YES	NO
Is the device life-supporting or life sustaining?		✓
Is the device implanted (short-term or long-term)?		✓
Does the device design use software?		✓
Is the device sterile?		✓
Is the device for single use?	✓	
Is the device for home use?	✓	
Is the device for prescription use?		✓
Does the device contain a drug or biological product as a component?		✓
Is this device a kit?		✓

Apex Medical Technologies, Inc., has provided labeling for the Avanti™ Condom, that satisfies our concerns for interim labeling required for new material condoms.

S1

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

The following serves to highlight and summarize the testing performed on this device to support a substantial equivalence determination.

Clinical Performance - Contraceptive Effectiveness

A clinical protocol to investigate the contraceptive effectiveness in a prospective clinical study has been approved by letter dated May 4, 1994.

Labeling

The labeling for the Avanti™ Condom has been resolved. (See Facsimile dated December 13, 1994, from Ms. Alice DePaul to Colin M. Pollard.) The company has provided labeling, pursuant to and in line with our November 21, 1994, notification. As background, the Center has determined that the labeling must reflect that the intended use for the device is limited to latex sensitive persons. Further, the labeling should indicate that the contraceptive effectiveness has not been determined, and that clinical trials to determine effectiveness are underway. This issue has been addressed by Apex Medical Technologies and the proposed labeling conforms with our November 21, 1994, letter and interim labeling.

Slippage and Breakage

The study submitted by Apex which supported that their breakage and slippage rate (for the Avanti™ condoms) is equivalent to the latex control has been determined to be acceptable.

Shelf Life

Don Marlowe reviewed the document for shelf life and stated that the compant will adhear to a test program to support the long term shelf life of the Avanti™ Thick Condom established for the original 510(k) for the Avanti™ Condom.

Viral Penetration (Barrier Properties)

Based on viral penetrations studies the worst case leak in a Avanti™ Condom led to a calculated hole size of 5μ, corrected for loss of virus challenge titer. The adjusted calculated hole size is comparable the a latex condom.

Chemistry

The Avanti™ condom is manufacturered using a thrmoplastic polyurethane, Estane 5767 supplied by B.F. Goodrich. Pellets of the polyurethane are dissolved in tetrahydrofuran (subsequently evaporates) and the condom is dipped onto mandrels. The application

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

contains information on the level of THF in the finished device. Dr. Tsai has reviewed this material and identified that the identified levels are acceptable.

Toxicology/Biocompatibility

The sponsor has conducted adequate biocompatibility tests on Avanti™ Condom and that the results of the testing show that the material is relatively safe for its intended use.

Quality Assurance

100% electronic hole detection is conducted using the previously validated Uson Corporation's Model 100, vacuum decay leak tester. The applicant has also conducted testing to validate this test unit (K871358, image p 38) that was accepted as an in-process detection system.

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

Quality Control Release Procedures

The quality control release testing is in accordance with Mil Std 105E, with water leak testing equivalent to ASTM D3492-89 at Level I, Normal, 0.4 AQL. Physical testing (tensile strength and elongation) at Level S-2, 2.5 AQL.

		YES	NO	
1.	IS PRODUCT A DEVICE?	✓		IF NO, STOP
2.	DEVICE SUBJECT TO 510(k)?	✓		IF NO, STOP
3.	SAME INDICATION STATEMENT?	✓		IF YES, GOTO 5
4.	DO DIFFERENCES ALTER THE EFFECT OR RAISE NEW ISSUES OF SAFETY OR EFFECTIVENESS?			IF YES,STOP->NSE
5.	SAME TECHNOLOGICAL CHARACTERISTICS?	✓		IF YES, GOTO 7
6.	COULD THE NEW CHARACTERISTICS AFFECT SAFETY OR EFFECTIVENESS?	✓		IF YES, GOTO 8
7.	DESCRIPTIVE CHARACTERISTICS PRECISE ENOUGH?			
8.	NEW TYPES OF SAFETY AND EFFECTIVENESS QUESTIONS?		✓	IF YES, STOP->NSE
9.	ACCEPTED SCIENTIFIC METHODS EXIST?	✓		IF NO,STOP->NSE
10.	PERFORMANCE DATA AVAILABLE?	✓		IF NO,REQ. DATA
11.	DATA DEMONSTRATE EQUIVALENCE	✓		IF YES, STOP->SE

* "yes" responses to 4, 6, 8, and 11, and every "no" response requires an explanation below

SCJ

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

Response to Question 5, 6, 8 and 11

5. SAME TECHNOLOGICAL CHARACTERISTICS?

This device does not have the same technological characteristics as a latex condom. The device material is a ponlyurethane material and as described above, and not natural latex rubber. As such the device does not exhibit many of the same sensitization problems as a latex condom and would, therefore, be acceptable for use by latex sensitive persons.

6. COULD THE NEW CHARACTERISTICS AFFECT SAFETY OR EFFECTIVENESS?

The new technological characteristics may affect the safety or effectiveness of this device when used as a contraceptive or as a prophylactic. Issues regarding the material property differences may compromise this device as a barrier or may affect its effectiveness in use.

8. NEW TYPES OF SAFETY AND EFFECTIVENESS QUESTIONS?

The questions raised above are not new questions of safety or effectiveness. Similar questions may arise for latex condom if there were significant changes in the device dimensions.

11. DATA DEMONSTRATE EQUIVALENCE

Significant issues regarding device testing have been addressed including the ability of the material to be a barrier to virus penetration, in-use slippage and breakage, material shelf life, toxicity of the material, etc.

The contraceptive effectiveness of this device is to be determined in a prospective, randomized clinical trial that has been approved under IDE G940041.

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

Recommendation:

The Avanti™ Thick Condom is substantially equivalent to the generic class latex condom.

ProCode: 85 HIS
Class: II
CFR #: 21 CFR § 884.5300

J. Michael Kuchinski Date: 1/17/95
Microbiologist (HFZ-470)
B:\K911431F.REV

Chief, Ob/Gyn Branch Date: 1/27/95

/✓/ Concur

/ / Do Not Concur

Comments:

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

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Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

M E M O R A N D U M
FOOD AND DRUG ADMINISTRATION
CENTER FOR DEVICES AND
RADIOLOGICAL HEALTH
OFFICE OF DEVICE EVALUATION

DATE: 01/17/95

FROM: Microbiologist (HFZ-470)

SUBJECT: Apec Medical Technologies (Avanti™ Thick Condom)

To: The Record - K922688/D

In this amendment, the sponsor, Apex Medical Technologies, Inc., has provided information requested in our letter dated, August 1, 1994. Our response requested the following:

(b) (4)

[redacted]

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

(b) (4)

[redacted]

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

(b) (4)

[redacted]

Recommendation:

The labeling revisions should be communicated to the applicant and a response should be requested. Labeling is the only remaining issue in this 510(k).

J. Michael Kuchinski (HFZ-470) 1/17/95
jmk B:\K922688D.REV:01/17/95

/ / Concur

Chief, OGDB Colin M. Pollard Date:

/ / Do not concur

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

NOV 21 1994

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

See Attachment for Addressees

This letter is a follow up to the labeling requirements fax'd to you last week for condoms made of polyurethane and other new materials (enclosure). As you know, the agency developed this policy, with input from the industry, to permit marketing of condoms that can be used by people allergic to latex, who otherwise have no alternative for protection from sexually transmitted diseases (STDs).

Although such new condoms will have undergone extensive laboratory testing and will have been evaluated for slippage and breakage, their effectiveness in actual use has not been tested. Normally, such testing would be required before a product is cleared for marketing. However, because of the potential risk to latex-sensitive people who might forego using a condom or mistakenly depend on a lambskin condom to provide STD protection, the FDA decided to clear these new condoms before completion of clinical trials that would establish in-use comparison to latex condoms.

While the clinical trials are ongoing, manufacturers will be required to state on the labeling that - as specified in the enclosure - the condom is intended to be used only when either partner is allergic to latex. Manufacturers will also be required to include a caution that, although laboratory testing has shown that particles as small as sperm and viruses will not pass through the material, clinical trials to assess effectiveness in preventing pregnancy and STDs have not been completed.

The enclosure specifies the language and format for both the principal display panel and the back panel of the retail package. This required information shall be displayed no less prominently than other consumer information on the package, such as the storage information or precautions.

This same required consumer labeling shall also be provided with any package insert.

As discussed at the October 4, 1994, FDA/Industry meeting, several 510(k)s for non-latex condoms were approved in previous years although no products were in commercial distribution. We have worked with the one manufacturer who has chosen to proceed to marketing at this time on interim labeling pending our decision on the wording contained in this communication. This manufacturer, London International, has agreed to amend their labeling to conform with that of other manufacturers as soon as such wording was available. In addition, their foil packaging contains older claims which will also conform to the new labeling requirements before the end of 1994.

We wish to thank you for your assistance in the development of this labeling and your participation in our recent meeting.

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

If you have any further questions on applying this labeling guidance to your condom for the completion of your 510(k) premarket notification, you may contact Mr. Colin M. Pollard, at 301-594-1180.

Sincerely yours,

Susan Alpert, Ph.D., M.D.
Director
Office of Device Evaluation
Center for Devices
and Radiological Health

Enclosure

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

INTERIM LABELING REQUIREMENTS FOR CONDOMS MADE FROM NEW MATERIALS

I. Principal Display Panel

The principal display panel (21 CFR §801.60) must display the following:

"For Latex Sensitive Condom Users"

This is a [Blank] condom. This is <u>not</u> a latex condom. See Important Information on Back of Package.

II. Back Panel

The following *Important Consumer Information* must be placed on the back panel of the retail package, as well as within the package insert and with any promotional material:

Important Consumer Information: [Bold]

You may use this [Blank] condom if you or your partner are allergic to latex.

You should know:

- The risks of pregnancy and sexually transmitted diseases (STDs), including AIDS (HIV infection), are not known for this condom. A study is being done.
- There are laboratory tests on this [Blank] material. These tests show that organisms even as small as sperm and viruses like HIV cannot pass through it.

Latex condoms [Bold] for men, if used correctly with every act of vaginal intercourse, are highly effective at preventing pregnancy, as well as STDs, including AIDS (HIV infection).

CDRH/FDA: 10/25/94

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-06-2015

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 08, 1994

APEX MEDICAL TECHNOLOGIES, INC.
10064 MESA RIDGE CT.,
SUITE #202
SAN DIEGO, CA 92121
ATTN: ALICE A. DEPAUL

510(k) Number: K922688
Product: "EXTRA PROTECTION" POLYURETHANE CONDOM

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. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

K922688/S1

APEX MEDICAL TECHNOLOGIES, INC.

10064 Mesa Ridge Ct. • Suite #202
San Diego, CA 92121
(619) 535-0012 • FAX (619) 535-9715

September 1, 1994

Food and Drug Administration
Bureau of Medical Devices
Document Control Center (HFZ - 401)
1390 Piccard Drive
Rockville, MD 20850

RECEIVED
7 SEP 94 07 50
FDA/CDRH/OCE/DID

Re: K922688
Avanti ™ "Thick Condom"

Dear Sirs/Madam:

This letter is in response to Colin M. Pollard's letter of August 1, 1994 requesting additional information concerning the above-referenced 510(k) submission. This letter contains the requested information, as follows:

(b) (4)

[redacted]

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

(b) (4)

[redacted]

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(b) (4)

[redacted]

We consider our intent to market this thicker polyurethane condom confidential commercial information, and request that this information be considered as such by the FDA. Additionally, some details contained in this letter are confidential in nature. We request the removal of the proprietary details of this submission from any potential disclosure under the Freedom of Information Act.

Should you require further information relating to this amendment, please contact me at (619) 535-0165.

Sincerely,

Alice A. DePaul

Alice A. DePaul
Vice President

Attachments

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

Exhibit I

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

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Exhibit II

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

(b) (4)

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Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

RESPONSE TO FDA QUESTIONS CONCERNING IDE (b)(4)

(b)(4)

70

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APPENDIX A

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

(b)(4) Test Data

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APPENDIX B

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APPENDIX C

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APPENDIX D

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

CAUTION - Investigational Device. Limited by Federal law to investigational use.

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Records Disclosed under FOIA Request # 2015-1976; Released by CDRH on 03-20-2015

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

August 12, 1994

APEX MEDICAL TECHNOLOGIES, INC.
10064 MESA RIDGE CT.,
SUITE #202
SAN DIEGO, CA 92121
ATTN: ALICE A. DEPAUL

510(k) Number: K922688
Product: "EXTRA PROTECTION" POLYURETHANE CONDOM

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. Please remember that all correspondence concerning your submission MUST be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefax material as part of your official premarket notification submission unless specifically requested of you by an FDA official.

If after 30 days the requested information is not received, we will discontinue review of your submission and proceed to delete 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 your submission will be considered a new premarket notification submission.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisor Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

510(K) ROUTE SLIP

510(k) NUMBER K922688 PANEL OB DIVISION DRAER BRANCH

TRADE NAME "EXTRA PROTECTION" POLYURETHANE CONDOM

COMMON NAME

PRODUCT CODE

APPLICANT APEX MEDICAL TECHNOLOGIES, INC.
SHORT NAME APEXMEDITECH
CONTACT ALICE A DEPAUL
DIVISION
ADDRESS 10064 MESA RIDGE CT.,
SUITE #202
SAN DIEGO, CA 92121
PHONE NO. ( ) - FAX NO. ( ) -

MANUFACTURER SCHMID LABORATORIES REGISTRATION NO. 1045600

DATE ON SUBMISSION 29-MAY-92 DATE DUE TO 510(K) STAFF

DATE RECEIVED IN ODE 04-JUN-92 DATE DECISION DUE 06-JUL-93

DECISION DECISION DATE

SUPPLEMENTS	SUBMITTED	RECEIVED	DUE POS	DUE	OUT
S003	02-AUG-94	03-AUG-94	17-OCT-94	01-NOV-94	12-AUG-94
S001	06-APR-93	07-APR-93	06-JUL-93	04-MAR-94	
S002	19-APR-94	21-APR-94	05-JUL-94	20-JUL-94	01-AUG-94

CORRESPONDENCE	SENT	DUE BACK	
C002	04-MAR-94	03-APR-94	HOLD LETTER
C003	01-AUG-94	31-AUG-94	HOLD LETTER
C001	03-SEP-92	02-JAN-93	HOLD LETTER
C004	12-AUG-94	11-SEP-94	HOLD LETTER

OTHER SUBMISSIONS	SUBMITTED	RECEIVED	DUE POS	DUE	OUT
ADD-TO-FILE	09-FEB-94	14-FEB-94			
ADD-TO-FILE	30-SEP-93	06-OCT-93			
ADD-TO-FILE	20-OCT-93	28-OCT-93			

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

510(K) ROUTE SLIP

DD-TO-FILE	25-JAN-94	02-FEB-94

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

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service
Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

Memorandum

Date

om REVIEWER(S) - NAME(S) Kuchinski (HFR-470)

Subject 510(k) NOTIFICATION K922688/S3

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. See letter on 8/2/94 - NOT responsive to 8/1/94 letter

_____ (D) Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Additional Comments:

Is this device subject to Postmarket Surveillance? Yes ☐ No ☐

This 510(k) contains: (check appropriate box(es))

☐ A 510(k) summary of safety and effectiveness, or

☐ A 510(k) statement that safety and effectiveness information will be made available

☐ The required certification and summary for class III devices

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:

_____

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

_____

REVIEW: Colin M. Pollard (BRANCH CHIEF) OGDB (BRANCH CODE) 8/11/94 (DATE)

FINAL REVIEW: _____ (DIVISION DIRECTOR) (DATE)

*DOES NOT APPLY TO ANY "SE" DECISIONS Revised 11/18/91

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

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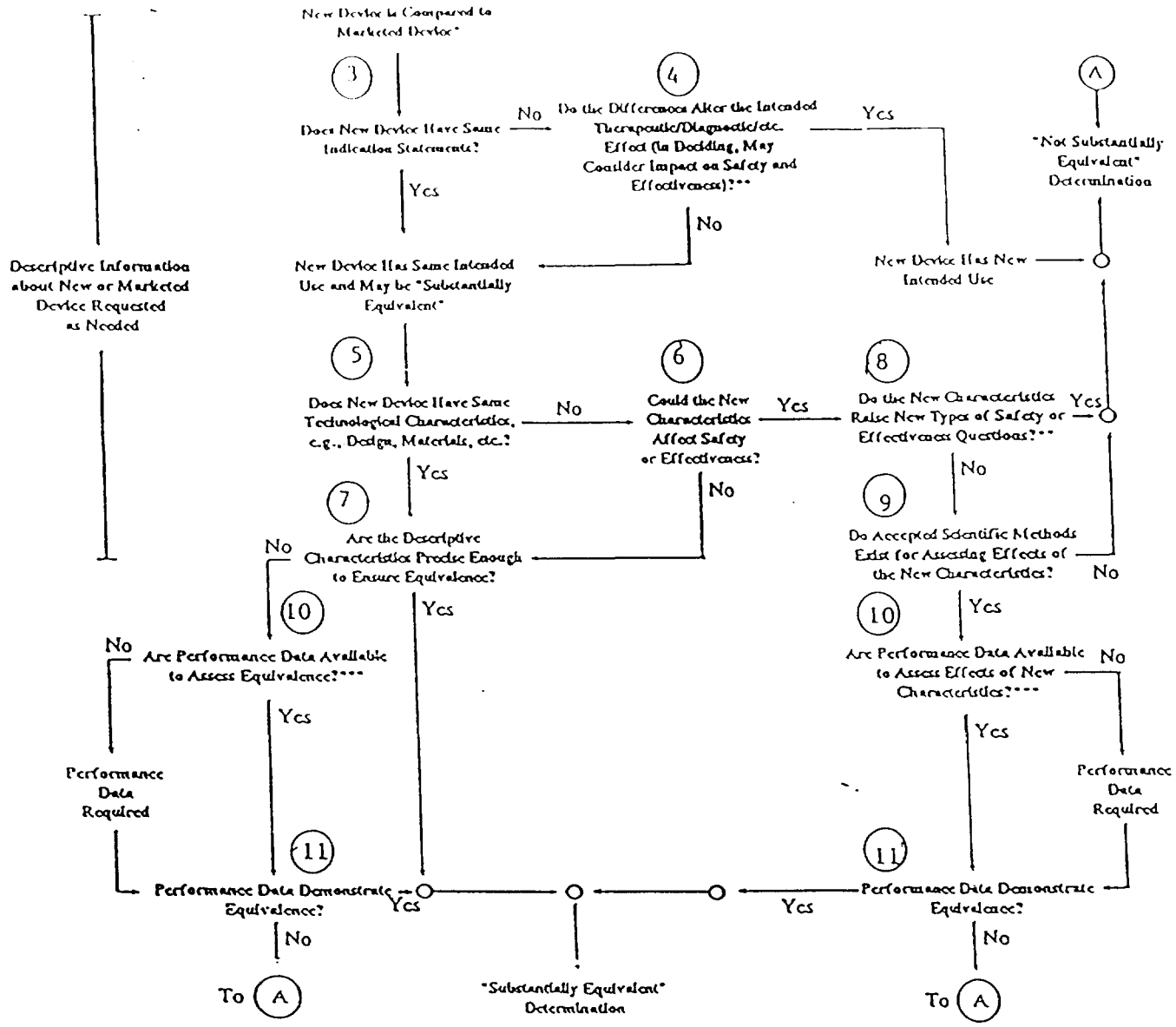
Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

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.

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

I N T E R O F F I C E M E M O R A N D U M

Date: 11-Aug-1994 01:56pm EDT
From: C. David Lytle
CDL
Dept: OST-DLS
Tel No: 443-7184

TO: John M. Kuchinski (JMK)

CC: Melvin E. Stratmeyer (MES)
CC: Mary Elizabeth Jacobs (MEJ)

Subject: K922688

Mike,

I believe the viral barrier tests are complete now.

Cheers, Dave

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

Comments on K922688/B - Avanti Thick Condom by Apex Medical Tech.
C.D. Lytle - 8/11/94 (rec'd 8/10/94)

(b) (4)

[redacted]

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

DIVISION OF REPRODUCTIVE, ABDOMINAL, EAR, NOSE AND THROAT
AND RADIOLOGICAL DEVICES

MEMORANDUM OF TELEPHONE CONVERSATION

BETWEEN: J. Michael Kuchinski Date: 08/02/94

AND: Ms. Alice A. DePaul

TITLE: Vice President

COMPANY: Apex Medical Technologies, Inc.

PHONE NUMBER: (619) 535-0165

FAX NUMBER:
(if applicable)

DOCUMENT NUMBER: K922688/S3
(if applicable)

(b) (4)

[redacted]

Signed:
J. Michael Kuchinski

Original to: K922688/S3
Copy to: Chron

SLJ/RRG 11/20/92 Rev. 3/30/94

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

334

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

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

August 04, 1994

APEX MEDICAL TECHNOLOGIES, INC.
10064 MESA RIDGE CT.,
SUITE #202
SAN DIEGO, CA 92121
ATTN: ALICE A. DEPAUL

510(k) Number: K922688
Product: "EXTRA PROTECTION" POLYURETHANE CONDOM

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. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

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

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10064 Mesa Ridge Ct. • Suite #202
San Diego, CA 92121
(619) 535-0012 • FAX (619) 535-9715

RECEIVED
3 AUG 94 15 34
FDA/CDRH/ODE/DMC

August 2, 1994

Food and Drug Administration
Bureau of Medical Devices
Document Control Center (HFZ - 401)
1390 Piccard Drive
Rockville, MD 20850

Re: ~~K9226888~~ K922688/S3
Avanti ™ "Thick Condom"

Dear Sirs/Madam:

This letter is in response to Michael Kuchinski's June 6, 1994 request for additional information concerning our latest response to Lillian Yin's letter of March 8, 1994 requesting additional information on the above-referenced 510(k) submission. During a June 6, 1994 tele-conference among Michael Kuchinski of FDA, Dr. Lytal of FDA, a[redacted] (b) (4) [redacted], it was agreed that additional clarification was needed on Question 1, part a) concerning (b) (4) [redacted]. This letter contains the clarification.

(b) (4)
[redacted]

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

(b) (4)

[redacted]

We consider our intent to market this thicker polyurethane condom confidential commercial information, and request that this information be considered as such by the FDA. Additionally, some details contained in this letter are confidential in nature. We request the removal of the proprietary details of this submission from any potential disclosure under the Freedom of Information Act.

Should you require further information relating to this amendment, please contact me at (619) 535-0165.

Sincerely,

Alice A. DePaul

Alice A. DePaul
Vice President

Attachment

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

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

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10064 Mesa Ridge Ct. • Suite #202
San Diego, CA 92121
(619) 535-0012 • FAX (619) 535-9715

RECEIVED
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FDA/CDRH/ODE/DMC

August 2, 1994

Food and Drug Administration
Bureau of Medical Devices
Document Control Center (HFZ - 401)
1390 Piccard Drive
Rockville, MD 20850

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(b) (4)
[redacted]

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

329

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

(b) (4)

[redacted]

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Sincerely,

Alice A. DePaul

Alice A. DePaul
Vice President

Attachment

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

(b)(4) Schematic

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Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville MD 20850

AUG - 1 1994

Ms. Alice A. DePaul
Vice President
Apex Medical Technologies, Inc.
10064 Mesa Ridge Court
Suite 202
San Diego, California 92121

Re: K922688/B
Avanti™ "Thick Condom"
Dated: April 19, 1994
Received: April 21, 1994

Dear Ms. Alice A. DePaul:

We have reviewed your Section 510(k) notification of intent to market the device referenced above. Even though you have responded to our letter of March 8, 1994, your response to questions, 1, 4 and 6 were not adequate. Therefore, 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 the following additional information:

(b) (4)

[redacted]

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

(b) (4)

[redacted]

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

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(f) and (h), and you have received a letter from FDA allowing you to do so. 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 exemption (IDE) regulations.

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

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

If the 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.

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

If you have any questions concerning the contents of this letter, please contact Mr. J. Michael Kuchinski at (301) 594-1180. 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,

Ralph Kammula

Colin M. Pollard
Chief, Obstetrics/Gynecology Devices Branch
Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

510(K) ROUTE SLIP

510(k) NUMBER K922688 PANEL OB DIVISION DRAER BRANCH

TRADE NAME "EXTRA PROTECTION" POLYURETHANE CONDOM

COMMON NAME

PRODUCT CODE

APPLICANT APEX MEDICAL TECHNOLOGIES, INC.
SHORT NAME APEXMEDITECH
CONTACT ALICE A DEPAUL
DIVISION
ADDRESS 10064 MESA RIDGE CT.,
SUITE #202
SAN DIEGO, CA 92121
PHONE NO. (___) ___-____ FAX NO. (___) ___-____

MANUFACTURER SCHMID LABORATORIES REGISTRATION NO. 1045600

DATE ON SUBMISSION 29-MAY-92 DATE DUE TO 510(K) STAFF

DATE RECEIVED IN ODE 04-JUN-92 DATE DECISION DUE 06-JUL-93

DECISION DECISION DATE

SUPPLEMENTS	SUBMITTED	RECEIVED	DUE POS	DUE	OUT
S001	06-APR-93	07-APR-93	06-JUL-93	04-MAR-94	
S002	19-APR-94	21-APR-94	05-JUL-94	20-JUL-94	01-AUG-94

CORRESPONDENCE	SENT	DUE BACK	
C002	04-MAR-94	03-APR-94	HOLD LETTER
C003	01-AUG-94	31-AUG-94	HOLD LETTER
C001	03-SEP-92	02-JAN-93	HOLD LETTER

OTHER SUBMISSIONS	SUBMITTED	RECEIVED	DUE POS	DUE	OUT
ADD-TO-FILE	09-FEB-94	14-FEB-94			
ADD-TO-FILE	30-SEP-93	06-OCT-93			
ADD-TO-FILE	20-OCT-93	28-OCT-93			
ADD-TO-FILE	25-JAN-94	02-FEB-94			

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

545

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

Ms. Alice A. DePaul
Vice President
Apex Medical Technologies, Inc.
10064 Mesa Ridge Court
Suite 202
San Diego, California 92121

Re: K922688/B
Avanti™ "Thick Condom"
Dated: April 19, 1994
Received: April 21, 1994

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(b) (4)

[redacted]

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

(b) (4)

[redacted]

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

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Document Mail Center (HFZ-401)
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Sincerely yours,

Colin M. Pollard
Chief, Obstetrics/Gynecology Devices Branch
Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ-470 Division
D.O.

A:\K922688B.AI:MKuchinski:07/26/94
Revised:07/27/94:cmp
Revised:07/28/94:cmp
Final:JulietteMoussa:07/29/94

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
Z470	Kuchinski	7/29						

☆ U.S. GOVERNMENT PRINTING OFFICE 1991-519-771

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

398

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Memorandum

Date

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

Subject 510(k) NOTIFICATION K922688/S2

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:

Is this device subject to Postmarket Surveillance? Yes ☐ No ☐

This 510(k) contains: (check appropriate box(es))

☐ A 510(k) summary of safety and effectiveness, or

☐ A 510(k) statement that safety and effectiveness information will be made available

☐ The required certification and summary for class III devices

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:

_____

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

_____

REVIEW: Raju G Kommuru (BRANCH CHIEF) | OGDB (BRANCH CODE) | 7/28/94 (DATE)

FINAL REVIEW: _____ (DIVISION DIRECTOR) (DATE)

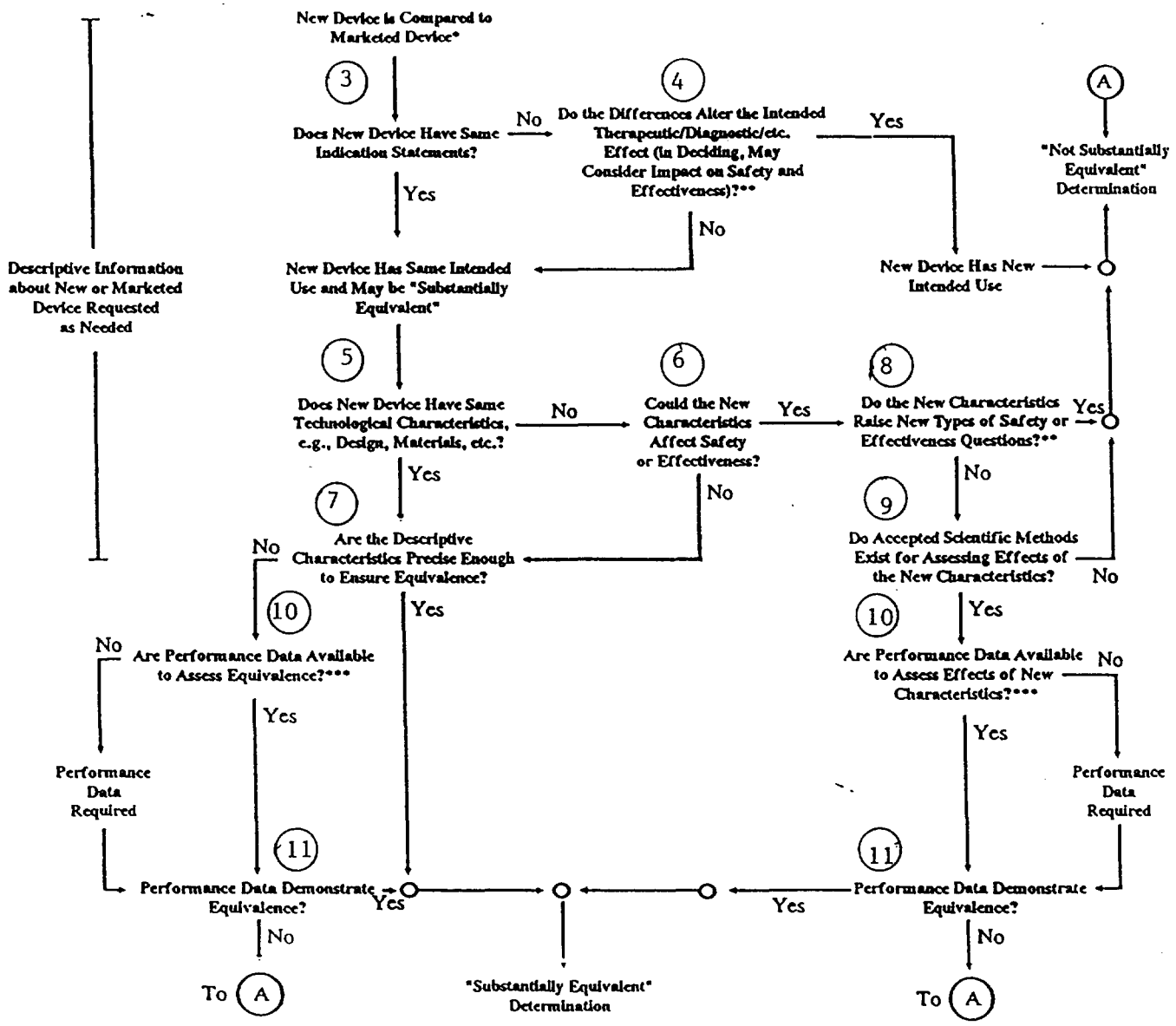
*DOES NOT APPLY TO ANY "SE" DECISIONS — Revised 11/18/91

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

349

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

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.

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

M E M O R A N D U M

FOOD AND DRUG ADMINISTRATION
CENTER FOR DEVICES AND
RADIOLOGICAL HEALTH
OFFICE OF DEVICE EVALUATION

DATE: 07/27/94

FROM: Microbiologist (HFZ-470)

SUBJECT: Avanti™ "Thick Condom"

To: The Record - K922688/B

In this amendment, the sponsor, Apex Medical Technologies, Inc., has provided the following information requested in our letter dated: March 8, 1994.

(b) (4)

[redacted]

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

351

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

(b) (4)

[redacted]

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

352

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

(b) (4)

[redacted]

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

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(b) (4)

[redacted]

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

(b) (4)

[redacted]

Recommendation:

Additional information is necesary in order to complete the file.

J. Michael Kuchinski 7/28/94

J. Michael Kuchinski (HFZ-470)
jmk B:\K922688B.REV:07/28/94

Chief, OGDB Date:
Colin M. Pollard

/ / Concur

/ / Do not concur

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

355

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

DIVISION OF REPRODUCTIVE, ABDOMINAL, EAR, NOSE AND THROAT
AND RADIOLOGICAL DEVICES

MEMORANDUM OF TELEPHONE CONVERSATION

BETWEEN: Mr. J. Michael Kuchinski Date: 07/25/94

AND: Ms. Phyliss Barber

TITLE: Vice President

COMPANY: London International, U.S. Holdings

PHONE NUMBER: (813) 364-7159

FAX NUMBER:
(if applicable)

DOCUMENT NUMBER: K922688/B
(if applicable)

(b) (4)

[redacted]

Signed: J. Michael Kuchinski

Original to: K922688
Copy to: K932245
Chron

SLJ/RRG 11/20/92 Rev. 3/30/94

356

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

DIVISION OF REPRODUCTIVE, ABDOMINAL, EAR, NOSE AND THROAT
AND RADIOLOGICAL DEVICES

MEMORANDUM OF TELEPHONE CONVERSATION

BETWEEN: J. Michael Kuchinski (HFZ-470) Date: June 6, 1994
David Lytle (HFZ-112)
AND: Jerry Nelson and Timm Dunn

TITLE:

COMPANY: Nelson Laboratories, Inc

PHONE NUMBER: (801) 272-5353

FAX NUMBER:
(if applicable)

DOCUMENT NUMBER: K922688/A
(if applicable)

SUMMARY:

(b) (4)

[redacted]

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

(b) (4)

[redacted]

Signed: _____

Original to: File K922688/B
Copy to: Chron

SLJ/RRG 11/20/92 Rev. 3/30/94

358

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

(b) (4)

[redacted]

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

I N T E R O F F I C E M E M O R A N D U M

Date: 23-May-1994 11:47am EDT
From: Bruce A. Herman
BAH
Dept: OST-DPS
Tel No: 443-6113

TO: John M. Kuchinski (JMK)

CC: C. David Lytle (CDL)
CC: W. Howard Cyr (HWC)

Subject: Avanti Condom

MEMO:

Date: May 23, 1994
From: Bruce A. Herman (BAH) 443-6113
To: John M. Kuchinski (JMK)

CC: C. David Lytle (CDL)
CC: W. Howard Cyr (HWC)

Subject: K922688/B - Avanti Thick Condom

(b) (4)

[redacted]

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

360

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

I N T E R O F F I C E M E M O R A N D U M

Date: 18-May-1994 09:33am EDT
From: C. David Lytle
CDL
Dept: OST-DLS
Tel No: 443-7184

TO: John M. Kuchinski (JMK)

CC: Bruce A. Herman (BAH)
CC: Mary Elizabeth Jacobs (MEJ)
CC: Melvin E. Stratmeyer (MES)

Subject: Review of K922688/B

(b) (4)

[redacted]

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

(b) (4)

[redacted]

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

ODE/DRAERD
REQUEST FOR CONSULTATION

FROM: J. Michael Kuchinski TO: Richard Kotz

THROUGH: Colin M. Pollard 5/12/94 THROUGH: Harry Bushar, Ph.D.

510(K) NO. K922688/B Manufacturer: Apex Medical Tech.

DEVICE: Avanti™ Thick Condom

DESIRED COMPLETION DATE: June 1, 1993 or ASAP

REASON FOR REQUEST

- ☐ NEW SUBMISSION
- ☐ MODIFIED PROTOCOL
- ☐ NEW MATERIALS
- ☐ MODIFIED MANUFACTURING
- [X] RESPONSE TO DEFICIENCY LETTER
- ☐ MODIFIED DESIGN
- ☐ **LABELING**
- ☐ OTHER

TYPE OF REQUEST

- ☐ ENGINEERING REVIEW
- ☐ STERILITY REVIEW
- ☐ **CLINICAL REVIEW**
- ☐ **LABELING REVIEW**
- ☐ MATERIALS REVIEW
- ☐ TOXICOLOGY REVIEW
- [X] STATISTICAL REVIEW
- ☐ OTHER REVIEW

COMMENTS/SPECIAL INSTRUCTIONS

(b) (4)

[redacted]

J. Michael Kuchinski 5/12/94

SIGNATURE OF REQUESTER **DATE**

B:\K922688/B.CON

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

365

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

ODE/DRAERD
REQUEST FOR CONSULTATION

FROM: J. Michael Kuchinski TO: David Lytle, Ph.D.

THROUGH: Colin M. Pollard 5/12/94 THROUGH: _____

510(K) NO. K922688/B Manufacturer: Apex Medical Tech.

DEVICE: Avanti™ Thick Condom

DESIRED COMPLETION DATE: June 1, 1993 or ASAP

REASON FOR REQUEST

- ☐ NEW SUBMISSION
- ☐ MODIFIED PROTOCOL
- ☐ NEW MATERIALS
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- [X] RESPONSE TO DEFICIENCY LETTER
- ☐ MODIFIED DESIGN
- ☐ **LABELING**
- ☐ OTHER

TYPE OF REQUEST

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- ☐ STERILITY REVIEW
- ☐ **CLINICAL REVIEW**
- ☐ **LABELING REVIEW**
- ☐ MATERIALS REVIEW
- ☐ TOXICOLOGY REVIEW
- ☐ STATISTICAL REVIEW
- [X] OTHER REVIEW (Permeability Assay)

COMMENTS/SPECIAL INSTRUCTIONS

(b) (4)

[redacted]

J. Michael Kuchinski 5/12/94

SIGNATURE OF REQUESTER **DATE**

B:\K922688/B.CON

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

369

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

ODE/DRAERD
REQUEST FOR CONSULTATION

FROM: J. Michael Kuchinski TO: Eugene Williams, M.D.

THROUGH: Colin M. Pollard CMP 5/12/94 THROUGH: Lillian Yin, Ph.D.

510(K) NO. K922688/B Manufacturer: Apex Medical Tech.

DEVICE: Avanti™ Thick Condom

DESIRED COMPLETION DATE: June 1, 1993 or ASAP

REASON FOR REQUEST

- ☐ NEW SUBMISSION
- ☐ MODIFIED PROTOCOL
- ☐ NEW MATERIALS
- ☐ MODIFIED MANUFACTURING
- [X] RESPONSE TO DEFICIENCY LETTER
- ☐ MODIFIED DESIGN
- ☐ **LABELING**
- ☐ OTHER

TYPE OF REQUEST

- ☐ ENGINEERING REVIEW
- ☐ STERILITY REVIEW
- [X] **CLINICAL REVIEW**
- ☐ **LABELING REVIEW**
- ☐ MATERIALS REVIEW
- ☐ TOXICOLOGY REVIEW
- ☐ REVIEW
- ☐ OTHER REVIEW

COMMENTS/SPECIAL INSTRUCTIONS

(b) (4)

[redacted]

J. Michael Kuchinski 5/12/94

SIGNATURE OF REQUESTER **DATE**

B:\K922688/B.CON

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

365

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

ODE/DRAERD
REQUEST FOR CONSULTATION

FROM: J. Michael Kuchinski TO: Bruce Herman

THROUGH: Colin M. Pollard CMP 5/12/94 THROUGH: _____

510(K) NO. K922688/B Manufacturer: Apex Medical Tech.

DEVICE: Avanti™ Thick Condom

DESIRED COMPLETION DATE: June 1, 1993 or ASAP

REASON FOR REQUEST

- ☐ NEW SUBMISSION
- ☐ MODIFIED PROTOCOL
- ☐ NEW MATERIALS
- ☐ MODIFIED MANUFACTURING
- [X] RESPONSE TO DEFICIENCY LETTER
- ☐ MODIFIED DESIGN
- ☐ **LABELING**
- ☐ OTHER

TYPE OF REQUEST

- [X] ENGINEERING REVIEW
- ☐ STERILITY REVIEW
- ☐ **CLINICAL REVIEW**
- ☐ **LABELING REVIEW**
- ☐ MATERIALS REVIEW
- ☐ TOXICOLOGY REVIEW
- ☐ STATISTICAL REVIEW
- [X] OTHER REVIEW (Permeability Assay)

COMMENTS/SPECIAL INSTRUCTIONS

(b) (4)

[redacted]

J. Michael Kuchinski 5/12/94

SIGNATURE OF REQUESTER **DATE**

B:\K922688/B.CON

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville MD 20850

MAY 4 1994

Ms. Phyliss Barber
Vice President
London International Group
1819 Main Street, Suite 800
Sarasota, Florida 34236

Re: G940041
Study on the Feasibility, Acceptability and Safety
of a Non-Latex (Polyurethane) Male Condom
Dated: April 1, 1994
Received: April 4, 1994

Dear Ms. Barber:

The Food and Drug Administration (FDA) has reviewed your investigational device exemptions (IDE) application. Your application is conditionally approved, and you may begin your investigation, using a revised informed consent document which corrects (b) (4) [redacted] where you have obtained institutional review board (IRB) approval and submitted certification of IRB approval to FDA. Your investigation is limited to (b) (4) [redacted]

This approval is being granted on the condition that, within 45 days from the date of this letter, you submit information correcting the following deficiencies:

(b) (4) [redacted]

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

367

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(b) (4)

[redacted]

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

368

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

(b) (4)

[redacted]

This information should be identified as an IDE supplement referencing the IDE number above, and must be submitted in triplicate to:

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

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

If you do not provide this information within 45 days from the date of this letter, we may take steps to propose withdrawal of approval of your IDE application.

We would like to point out that FDA approval of your IDE application does not imply that this investigation will develop sufficient safety and effectiveness data to assure a determination of substantial equivalence of a premarket notification (510(k)) submission.

We have enclosed the guidance document entitled "Sponsor Responsibilities for a Significant Risk Device Investigation" to help you understand the functions and duties of a sponsor.

If you have any questions, please contact Mr. Colin M. Pollard at (301) 594-1180.

Sincerely yours,

David G. Seymour

for Lillian Yin, Ph.D.
Director, Division of Reproductive, Abdominal, Ear, Nose and Throat, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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

370

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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

May 04, 1994

APEX MEDICAL TECHNOLOGIES, INC.
10064 MESA RIDGE CT.,
SUITE #202
SAN DIEGO, CA 92121
ATTN: ALICE A. DEPAUL

510(k) Number: K922688
Product: "EXTRA PROTECTION" POLYURETHANE CONDOM

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. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

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

371

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

K922688/S2

10064 Mesa Ridge Ct. • Suite #202
San Diego, CA 92121
(619) 535-0012 • FAX (619) 535-9715

April 19, 1994

RECEIVED
21 APR 94 20 1 46 Z
FDA/CDRH/ODE/DMC

Food and Drug Administration
Bureau of Medical Devices
Document Control Center (HFZ - 401)
1390 Piccard Drive
Rockville, MD 20850

Re: K922688
Avanti™ "Thick Condom"

Dear Sirs/Madam:

This letter is in response to Lillian Yin's letter of March 8, 1994 requesting additional information on the above-referenced 510(k) submission. The following information corresponds directly with Dr. Yin's questions.

(b) (4)

[redacted]

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

(b) (4)

[redacted]

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

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Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

(b) (4)

[redacted]

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(b) (4)

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Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

(b) (4)

[redacted]

We consider our intent to market this thicker polyurethane condom confidential commercial information, and request that this information be considered as such by the FDA. Additionally, some details contained in this letter are confidential in nature. We request the removal of the proprietary details of this submission from any potential disclosure under the Freedom of Information Act.

Should you require further information relating to this amendment, please contact me at (619) 535-0165.

Sincerely,

Alice A. DePaul

Alice A. DePaul
Vice President

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

APPENDIX A

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

6.

FOR INFORMATION ONLY

6.2 Freedom from Holes and Visual Defects

Note: Refer to QA/SOP/A/132 - 'Use of freedom from holes test equipment'.

6.2.1 125 condoms will be examined for freedom from holes and visual defects.

6.2.2 Examine the condom for the presence of the following visual defects:

6.2.2.1 Broken or distorted bead

6.2.2.2 Foreign matter embedded in the condom.

6.2.2.3 Lumps of surplus material.

6.2.2.4 Bubbles.

6.2.2.5 Permanent creases with adhesion of the film.

6.2.2.6 Thin spots.

6.2.2.7 Abrasion or other surface damage.

6.2.3 Record the defects for each condom by placing a tick in the appropriate column on the quality control form and record the total number of condoms with defects

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

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Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

6.2.4 Examine the condom for the presence of visible holes and tears.

6.2.5 Make a record of any condom having a visible hole or tear by placing a tick in the appropriate column on the quality control form. Also note the position of the hole.

6.2.6 If no holes or tears are detected in a condom proceed to 6.2.7, otherwise discontinue the test.

6.2.7 Take the condom by the bead and load over the plastic holding collar on the water-test unit.

6.2.8 Turn the water-test unit around one place using the foot pedal. This will automatically fill the condom with 300 ± 10 ml of water.

6.2.9 Inspect the condom for hanging holes after at least one minute from the time of filling with water.

6.2.10 Make a record of any condom having a hanging hole by placing a tick in the appropriate column on the quality control form and discontinue the test on that condom. Also note the position of the hole.

6.2.11 If no leak is seen remove the condom from the mount and close the open end by twisting the condom near the bead.

6.2.12 Dry the outside of the condom using a tissue prior to laying it lengthways on the rolling test pad.

6.2.13 Use one hand to compress the condom and roll it firmly back and forth two to three times on a sheet of dry blotting paper, ensuring that all of the body contacts the paper at least once, and inspect the absorbent paper for water marks indicating leakage.

6.2.14 Squeeze the upper section of the condom so that water is forced into the shoulder/teat area of the condom then wipe this part of the condom on the blotting paper and inspect the absorbent paper for water marks indicating leakage.

6.2.15 Make a record of any condom having a rolling hole by placing a tick in the appropriate column on the quality control form. Also note the position of the hole.

FOR INFORMATION ONLY

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

6.2.16 Record the total number of condoms having visible holes/tears, hanging holes or rolling holes on the quality control report.

FOR INFORMATION ONLY

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

384

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

APPENDIX B

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

(b)(4) Test Data

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

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

(b)(4) Test Data

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

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

(b)(4) Test Data

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(b)(4) Test Data

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(b)(4) Test Data

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

(b)(4) Test Data

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

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

(b)(4) Test Data

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

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

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(b)(4) Test Data

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(b)(4) Test Data

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

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(b)(4) Test Data

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

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

(b)(4) Test Data

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

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

(b)(4) Test Data

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

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

Product Code: FHA; Request Date: 09-15-2016; Released by CDRH on 09-03-2015

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville MD 20850

MAR 8 1994

MAR 8 1994

Mr. Mark McGlothlin
President
Apex Medical Technologies, Inc.
10064 Mesa Ridge Court
Suite 202
San Diego, California 92121

Re: K922688/A
Avanti™ "Thick Condom"
Dated: April 6, 1993
Received: April 7, 1993

Dear Mr. McGlothlin:

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 the following additional information:

(b) (4)

[redacted]

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

404

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

(b) (4)

[redacted]

We believe that this information is necessary for use to determine whether or not this device is substantially equivalent to a legally marketed predicate device with regard to its safety and effectiveness.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(f) and (h), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the

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

40S

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

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 exemption (IDE) regulations.

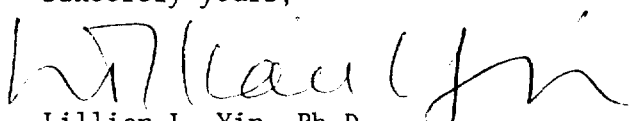
The requested information should reference your above 510(k) number and should be submitted to:

Food and Drug Administration
Center for Devices and
Radiological Health
1390 Piccard Drive
Rockville, Maryland 20850

If the 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 Mr. J. Mike Kuchinski at (301) 594-1180. 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,



Lillian L. Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

510(K) ROUTE SLIP

510(k) NUMBER K922688 PANEL OB DIVISION DRAER BRANCH

TRADE NAME "EXTRA PROTECTION" POLYURETHANE CONDOM

COMMON NAME

PRODUCT CODE

APPLICANT APEX MEDICAL TECHNOLOGIES, INC.
SHORT NAME APEXMEDITECH
CONTACT ALICE A DEPAUL
DIVISION
ADDRESS 10064 MESA RIDGE CT.,
SUITE #202
SAN DIEGO, CA 92121
PHONE NO. ( ) - FAX NO. ( ) -

MANUFACTURER SCHMID LABORATORIES REGISTRATION NO. 1045600

DATE ON SUBMISSION 29-MAY-92 DATE DUE TO 510(K) STAFF

DATE RECEIVED IN ODE 04-JUN-92 DATE DECISION DUE 06-JUL-93

DECISION DECISION DATE

SUPPLEMENTS	SUBMITTED	RECEIVED	DUE POS	DUE	OUT
S001	06-APR-93	07-APR-93	06-JUL-93	04-MAR-94	

CORRESPONDENCE	SENT	DUE BACK	
C002	04-MAR-94	03-APR-94	HOLD LETTER
C001	03-SEP-92	02-JAN-93	HOLD LETTER

OTHER SUBMISSIONS	SUBMITTED	RECEIVED	DUE POS	DUE	OUT
ADD-TO-FILE	09-FEB-94	14-FEB-94			
ADD-TO-FILE	30-SEP-93	06-OCT-93			
ADD-TO-FILE	20-OCT-93	28-OCT-93			
ADD-TO-FILE	25-JAN-94	02-FEB-94			

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

Mr. Mark McGlothlin
President
Apex Medical Technologies, Inc.
10064 Mesa Ridge Court
Suite 202
San Diego, California 92121

Re: K922688/A
Avanti™ "Thick Condom"
Dated: April 6, 1993
Received: April 7, 1993

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(b) (4)

[redacted]

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

408

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

(b) (4)

[redacted]

We believe that this information is necessary for use to determine whether or not this device is substantially equivalent to a legally marketed predicate device with regard to its safety and effectiveness.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(f) and (h), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the

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

409

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

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 exemption (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
1390 Piccard Drive
Rockville, Maryland 20850

If the 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 Mr. J. Mike Kuchinski at (301) 594-1180. 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,

Lillian L. Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

ENCLOSURE
cc: HFZ-401
HFZ-404 510(k) Staff
HFZ-470 DRAERD
D.O.
Draft:BAStuart:JMK:3-2-94:Disk#1 A:\K922688A
Final:BAStuart:3-3-94

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
Z470	Kuchinski	3/3	DF470	Yin	3/7/94			
Z470	Kammerdiener	3/4						
Z470	Gates	3/4/94						

☆ U.S. GOVERNMENT PRINTING OFFICE 1991-519-771

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

410

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Memorandum

Date

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

Subject 510(k) NOTIFICATION K922688/A

To THE RECORD EXPEDITED REVIEW

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.)

Dated: April 6, Oct 20
Received: April 7, Oct 28

Additional Comments:

Is this device subject to Postmarket Surveillance? Yes ☐ No ☐

This 510(k) contains: (check appropriate box(es))

☐ A 510(k) summary of safety and effectiveness, or

☐ A 510(k) statement that safety and effectiveness information will be made available

☐ The required certification and summary for class III devices

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:

_____

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

_____

REVIEW: Reji Kammula (BRANCH CHIEF) | OGDB (BRANCH CODE) | 3/4/94 (DATE)

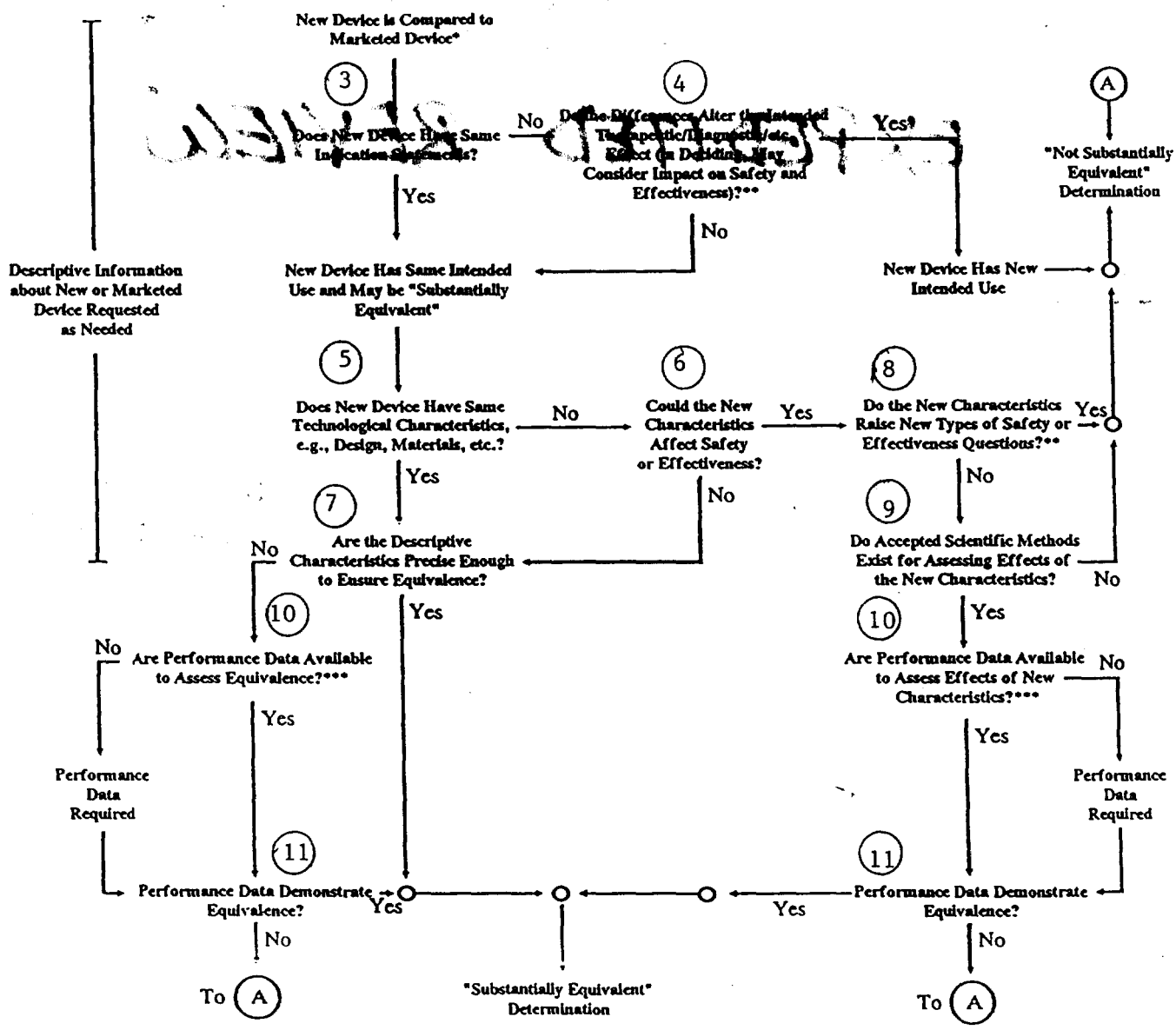
FINAL REVIEW: Alan Y. Li (DIVISION DIRECTOR) 3/4/94 (DATE)

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

DOES NOT APPLY TO ANY "SE" DECISIONS Revised 11/18/91

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

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.

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

K922688/A

Reviewer: J. Michael Kuchinski
Microbiologist

Division/Branch: DRAERD/ADOU/OGDB
(HFZ-470)

Proprietary Trade Name: Avanti™ "Thick Condom"

Classification Name: Condom, Polyurethane Condom, 21 CFR §884.5300

Common Name: Polyurethane Condom

Product to which compared: Apex Polyurethane Condom, K902936

Applicant: Apex Medical Technologies, Inc.
10064 Mesa Ridge Court
Suite 202
San Diego, California 92121

Contact: Ms. Alice DePaul
Vice President
Phone: (619) 535-0012

PRODUCT DESCRIPTION

It is the intention of the manufacturer, Apex Medical Technologies, Inc., to market a new device, Avanti™ "Thick Condom". The Avanti™ "Thick Condom" is male prophylactic condom made from polyurethane material. The device is to be introduced into commercial distribution through agreement with London International Group, plc, (parent company of Schmid Laboratories division of London International U.S. Holdings, Inc.). Initial location of the manufacturing site is to be Cambridge, ENGLAND, with subsequent manufacturing to be located in Anderson, South Carolina.

PREDICATE DEVICE and COMPARISON

The applicant has identified that this device is equivalent to the Apex Medical Technologies Avanti™ polyurethane condom found substantially equivalent, March 6, 1991, under K902936/A. The applicant also claims equivalence to latex condoms, specifically, the Lifestyles™ Extra Strength Condoms (Ansell) and to Trojan-Enz™ with Special Receptacle End (Carter-Wallace).

The device is a condom identified by the applicant as being identical in all but two aspects from that of the "standard thickness Avanti™ polyurethane condom" (identified in preceding paragraph.). The differences include:

- The nominal single wall thickness specification of the "Avanti™ Extra Protection Condoms" is 0.045 mm compared to 0.03 mm for the "standard thickness polyurethane condom". This increase in thickness is manifest in increases in some physical characteristic.

- The labeling has changed (from the original submission) to identify the condom as "Thick Condom" rather than "Extra Protection".

INTENDED USE

This device intended use is identified as being for contraception and prevention of transmission of STDs.

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

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DEVICE DESCRIPTION

The device is compared to both the Avanti™ (standard thickness) condom and to a natural rubber latex condom. A comparison table is presented on page 2 and provides a description of the device. The Avanti™ "Thick Condom" is identified as having the following physical characteristics and dimensions:

	Avanti™ "Thick"	Avanti™ Standard	Latex
Thickness (mm)	0.045-0.050	0.035-0.040	0.060
Width (flat) *	62-65 (rim 52mm)	62-65 (rim 52mm)	52
Peak Load (N) (Min Spec)	100	80	34
Tensile Strength (MPa)			
Min. Specification	55	55	17
Burst Pressure (kPa)			
Min. Specification	4.0	3.5	1.0
Burst Volume (L)	12.1 +/- 2.19		36.6 +/- 2.3
Min. Specification	9	7	15
Elongation (%)	564 +/- 3		783 +/- 27
Min. Specification	500	500	650
Tear Resistance (N/mm)	86.3 +/- 8.6		58.1 +/- 1.1

* Note the flat width of the sheath portion of the Avanti™ condom at 62-65 mm and the rim at 52 mm.

Comparison to the Standard Thickness Polyurethane Condom:

In our September 2, 1992, letter, questions extracted from the guidance for non-latex condoms were presented to the applicant. The overall request for information was modified so to allow for the applicant to certify that the certain device parameters (e.g., manufacturing change, material change, supplier change, etc.) had not changed from the device found SE under the 510K K902936/A, the standard thickness polyurethane condom. See Attachment I to this review for parameters where the applicant has provided certification (indicated by the *) that specification or device parameters have not changed. Also, where there is no certification the Attachment includes a brief description of differences.

The application includes comparative data from tensile strength testing and air burst testing comparing the "Extra Protection" Polyurethane Condom to the Standard Thickness Polyurethane Condom and to 2 latex condoms, "Trojan-Enz" and "Lifestyles Extra Strength". The following data has been presented:

	Thickness (mm)	Peak Load (N)	Tensile Strength (MPa)	Burst Pressure (kPa)
Extra Protection Condom	0.042-0.045	110.9	61.0	5.5
Standard Polyurethane Condom	0.028-0.035	86.1	60.8	3.88
Trojan-Enz	0.058-0.061	47.5	20.32	1.34
Extra Strength Lifestyles	0.082-0.105	105.23	25.08	1.72

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

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Chemistry:

Miin-Rong Tsai, Ph.D. has been consulted regarding the chemistry of this condom and he is satisfied that there is no detectable residual solvent as evidenced by the report from Truesdail Laboratories.

Quality Assurance:

Bruce Herman's review of the Avanti™ "Thick Condom" indicates that the application did not provide data from the water leakage tests conducted on the final product.

His comments are accurate, in that the applicant has not provided data, however, ODE has never required a 510(k) applicant to validate his water leakage test. The applicant has identified that the final device will undergo water leakage testing as final product release criteria to an AQL of 0.04. Also, test data from a water leakage test does not have much relevance since the leakage test is not a 100% test and only a statistical means of determining the acceptability of a lot. Also, the applicant has stipulated that the release of condom lots is at the 0.04 level. (Same as the latex condom AQL.)

Further, Don Marlow has commented on the QA for this condom and has accepted the data provided without comment. Dr. Herman's other question, a description of the final product release test is a valid request.

Clinical Slippage and Breakage:

Slippage and breakage of the Avanti™ compared to natural latex condoms were studied in a non-significant risk device investigation (participating couples purported not at risk of pregnancy (alternative contraceptive used) or at risk of contracting an STD). Each couple was supplied with either three (3) Avanti™ or 3 latex condoms and then were crossed over to use the other type. A total of 186 couples used latex condoms (474 condoms) and 199 couples used the Avanti™ condom (494 condoms) but only 49 couples used both types. Statistical consultation was requested, January 24, 1994 and Richard Kotz provided his review (attached) and made the following observations:

- the sample size for the clinical investigation must be justified in regard to pooling the data by showing that there is no significant difference between the demographic variables for the two groups; and,

- clinical consultation is necessary for the assumptions - breakage level at 5% and the acceptable clinical difference at 5%. (Richard thinks these are high.) The applicant should be asked for justification for these assumptions.

LABELING

The applicant has removed claims alluding to "Allergy Free" or hypoallergenic, BUT has included the term "Non-allergenic".

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

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The applicant should be advised of FDA's April 8, 1993 request for uniform labeling for condoms and the labeling should be revised to reflect the request.

The labeling makes a number of claims regarding the strength of the device, such as:

"...twice as strong as latex."
"Twice as strong as the best selling condom", etc.

As can be seen above, the Avanti™ Thick condom is stronger (as shown by peak load, tensile strength and burst pressure) than the Lifestyles Extra Strength condom.

	YES	NO
• Is the device life-supporting or life sustaining?	___	X
• Is the device implanted (short-term or long-term)?	___	X
• Does the device design use software?	___	X
• Is the device sterile?	___	X
• Is the device single use?	X	___
• Is the device home use?	X	___
• Is the device for prescription?	___	X
• Does the device contain a drug or biological product as a component?	___	X
• Is this device a kit?	___	X

Recommendation:

The following information will need to be requested from the applicant. These questions are not new, but have been raised during the review of the amended application material.

Permeability Testing

1. Review of the in-vitro permeability studies conducted on the Avanti™ "Thick Condom" by Nelson Laboratories has raised additional questions. Therefore, provide additional information on the experimental conditions from the in-vitro permeability studies, specifically, identify the dimensions of the condoms under pressure or identify the size of the restrainer. Also, provide the reason for the apparent difference in the volumes of challenge buffer added to each condom type and explain the differences in the volumes of challenge buffer added from one condom to another of the same type during the experiment.

2. Provide virus spike data for all condoms (both polyurethane types and the latex control) used in this test. In addition, the reported results indicate an approximate 50% loss of virus for either condom type, therefore, provide an explanation of this occurrence. Also, identify if the challenge virus titer remain at the stated levels for the 30 or 60 minute experiment.

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

Quality Assurance

3. Provide a detailed description of the test procedure identified as "Freedom from Holes" (BS 6001 Part 1; 1991) used to establish the quality of each condom lot or batch.

Labeling

4. In an April 8, 1993, letter to condom manufacturers (copy enclosed), FDA has requested that both sides of each individual condom package and the principal display panel of the outer box include the statement, "If used properly, latex condoms will help to reduce the risk of transmission of HIV infection (AIDS) and many other sexually transmitted diseases." This statement should be revised for your material and must be included on any package insert.

Slippage and Breakage

5. Provide justification for pooling the data submitted for the clinical investigation (breakage and slippage rates), by showing that there is no statistical difference between the demographic variables for the two groups. Also, provide justification for the statistical assumptions; breakage level at 5% and the acceptable clinical difference at 5%.

Clinical Performance

6. Please be advised that for all non-latex condoms, i.e., polyurethane or synthetic rubber, etc., FDA now requires clinical data demonstrating the contraceptive effectiveness. For 510(k)s already submitted, this requirement will be imposed via a post market study. However, before FDA will find your device to be substantially equivalent, you must present an acceptable post market clinical study plan.

   The clinical study plan should be submitted as a clinical protocol. Your protocol must include a clearly stated hypothesis with well-defined endpoints. The protocol must identify the nature of the control (male latex condoms), an appropriate study population and a clinically reasonable, multicenter, randomized protocol. Sample size calculations must include acceptable Type I and Type II error rates and identify an acceptable clinical difference in contraceptive rates between the control and experimental condoms. Proposed statistical methodology for analyzing the data should also be provided.

   The clinical study plan must include estimated time frames for initiating the study, collecting post market contraception data and for submitting study results.

J. Michael Kuchinski Date: 2/25/94

Chief, Ob/Gyn Branch Date:

/ / Concur

/ / Do Not Concur

Comments:

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

Attachment I - K922688/A

The following questions were put to the applicant by letter dated, September 2, 1992, and were extracted from the guidance for non-latex condoms. Questions were modified so to allow for the applicant to certify that certain device parameters (e.g., manufacturing change, material change, supplier change, etc.) have not been changed from the device found SE under the 510K K902936/A, the standard thickness polyurethane condom. The applicant has provided certification (indicated by the *) for some of the device parameters or has provided the response indicated.

1. Device Comparison

OK Compare your device, in tabular form, to a legally marketed device. This comparison should include, but should not be limited to, the intended use, material composition, device design, biocompatibility, dimensions, manufacturing process, physical specification, e.g., tensile strength, elongation, force at break, etc.

(See application page 2.)

2. General Information

* a. Provide a detailed description of the test procedures used by the manufacturer to establish the quality of each condom lot of batch. Additionally, identify when quality control tests are conducted during the manufacturing process.

b. Provide copies of labels, labeling and advertisements sufficient to describe the device directions for use. In addition, please be advised that statements that refer to qualitative properties of the device, i.e., "Clear and Sensitive", "Natural Feeling", and "No Odor", will need to be substantiated with data or must be deleted from the labeling.

(See Appendix B.)

3. Materials

a. Provide evidence that the raw materials specification (chemical and physical) and material suppliers are identical to those used for the standard thickness polyurethane condom, or provide a detailed description of the materials which should include:

* 1. molar ratio of component monomers for fabricating the material;

* 2. specification for the raw materials and a description of the quality control testing performed;

* 3. chemical composition and physical specifications of the material including molecular weight and molecular weight distribution; and

* 4. quantities of residual monomers and additives.

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

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4. Manufacturing

(b) (4)

OK

*

*

OK

OK

*

OK

*

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

* (b) (4) [redacted]

OK

5. Material Toxicity

* (b) (4) [redacted]

OK

*

5. Finished Product

OK a. Provide the device physical specifications including the length, width, thickness and mass.

See Review Section 2. Device Description (above) for description of the physical specifications for the Avanti™ Thick Condom. (See application Appendix G.)

OK b. Provide data from the following mechanical tests conducted on the final product:

See Review Section 2. Device Description (above) for data for the following physical specifications derived from mechanical tests for the Avanti™ Thick Condom. (See application Appendix G.)

1. elongation;

2. tear resistance and propagation;

3. air bust volume;

4. water leakage.

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

OK (b) (4)

[redacted]

6. Quality Assurance

(b) (4)

[redacted]

*

*

*

*

*

7. Packaging

* Provide a description of the package material specification if different from that used for the standard thickness polyurethane condom.

8. Shelf-Life

* Provide real-time and accelerated data to substantiate the shelf-life of the device, including an analysis for chemical degradation and mechanical properties over time under ideal conditions of temperature and humidity. The data should include a statistically valid sample size.

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

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9. Permeability

Provide data from the in-vitro permeability studies to demonstrate the barrier properties of the condom with respect to sexually transmitted diseases (STDs) of appropriate size and that test the device under conditions that simulate actual use.

(See Appendix H. and Dr. Lytle's review.)

10. Clinical Data

Provide the results from a clinical study with a statistically valid sample size, to demonstrate the performance of the devices during use. This should include the breakage rate of the condoms during use, the slippage rate of the condoms during use and any adverse reactions experienced by study subjects. Also, provide clinical data to substantiate the claim "Extra Protection".

(See Appendix C. and statistical review.)

Please be advised that FDA will not permit any claims, explicit or implied, that your condom is "Allergy Free" or hypoallergenic.

Labeling has been revised deleting reference to "allergy free and "hypoallergenic".

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

Freedom of Information Office Released by CDRH on 06-02-2015

Document Control No. K922688/A Principal Reviewer Kuemmerle

Date Assigned 4/21/93

- **Consulting reviews designated, as appropriate, by Branch Chief and lead reviewer, at the beginning of the review**

Specialty	Review Needed? Yes	No	Reviewer	Dates Sent	Returned
Clinical					
Engineering/ Physics	✓		Herman Marlow		Yes
Chemistry/ Biomaterials	•		Tsai personal communication		Yes
Biological/ Sterility	✓		Lytle		Yes
Toxicology/ Biocompatibility		✓			
Statistics	✓		Kotz		Yes.
Other					

==========

II. **Medical Officer sign-off to be signed at completion of all reviews and final-typed FDA letter -- Medical Officer sign-off is mandatory for documents requiring the Division Director's signature. Otherwise, the need for Medical Officer sign-off is left to the discretion of the Associate Director.**

I have reviewed the file and concluded that:

___ the clinical reviewer listed above has conducted an appropriate review, or

___ the medical aspects of this submission are such that a medical review is not required.

_____
Medical Officer

Effective date: August 21, 1992

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

MEDICAL TECHNOLOGIES, INC.

10064 Mesa Ridge Ct. • Suite #202
San Diego, CA 92121
(619) 535-0012 • FAX (619) 535-9715

RECEIVED
14 FEB 94 13 31
FDA/CDRH/ODE/DMC

February 9, 1994

Richard Kotz
Food and Drug Administration
Bureau of Medical Devices
Document Control Center (HFZ - 401)
1390 Piccard Drive
Rockville, MD 20850

Facsimile Number: 1-301-594-0050 8 total pages

Re: 510(k) K922688, Polyurethane Condom - Information Requested

Dear Mr. Kotz:

Per our telephone conversation of January 25, 1994, I am attaching a more detailed user study report, written by (b)(4) [redacted], which should answer the questions you asked.

Please call me at 1-619-535-0203 if you have any remaining questions, or if you need any clarification.

Sincerely,

Mark W. McGlothlin
President

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

(b)(4) Test Data

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

(b)(4) Test Data

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

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

(b)(4) Test Data

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

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

(b)(4) Test Data

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

(b)(4) Test Data

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

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

(b)(4) Test Data

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

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

(b)(4) Test Data

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date February 18, 1994

From Mathematical Statistician (Richard Kotz) HFZ-542
Statistics Branch, Division of Biometric Sciences, OSB

Subject Statistical Review of 510(k) K922688/A for the Avanti (Polyurethane) Condom, Apex Medical Tech Inc.

To Mike Kuchinski HFZ-470
Division of Reproductive, Abdominal, Ear, Nose, and Throat and Radiological Devices, ODE
Through: Director, Division of Biometric Sciences, OSB
Through: Chief, Statistics Branch, DBS, OSB

(b)(4) Test Data

[redacted]

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

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Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

If you have any questions, please call me at 594-0626.

Richard Kotz

Richard Kotz

cc: Lillian L. Yin, Ph.D. HFZ-470
Robert R. Gatling HFZ-470
Colin Pollard HFZ-470
Medical Device File
Board File

433

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

MEDICAL TECHNOLOGIES, INC.

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RECEIVED 2 FEB 94 09 23 FDA/CDRH/ODE/DMC

January 25, 1994

Colin Pollard
Food and Drug Administration
Bureau of Medical Devices
Document Control Center (HFZ - 401)
1390 Piccard Drive
Rockville, MD 20850

Facsimile Number: 1-301-594-2359 3 Pages

Re: Follow-up to request for expedited review for 510(k) K922688, Polyurethane Condom

Dear Mr. Pollard:

Over 90 days has now passed since we made our written request for obtaining an expedited review of 510(k) K922688, Polyurethane Condom, which you requested of us in our meeting of October 19, 1993. We still believe that there can be a significant public health benefit if this condom is put into the marketplace quickly, and we would appreciate FDA's cooperation by granting this request for expedited review. The basis for this request is contained in my October 20, 1993 letter to you. For your convenience, I have attached a copy of the original request.

Thank you in advance for giving this request your serious consideration. Please feel free to call me at 1-619-535-0203 if you have any remaining questions.

Sincerely,

Mark W. McGlothlin
President

Copies to: Phyliss Barber, LIUSH
Pamela Stratton, M.D. NICHD
William Potter, Ph.D., LIG

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

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10064 Mesa Ridge Ct. • Suite #202
San Diego, CA 92121
(619) 535-0012 • FAX (619) 535-9715

October 20, 1993

Colin Pollard
Food and Drug Administration
Bureau of Medical Devices
Document Control Center (HFZ - 401)
1390 Piccard Drive
Rockville, MD 20850

Facsimile Number: 1-301-594-2353 2 Pages

Re: REQUEST FOR EXPEDITED REVIEW
510(k) K922688 Polyurethane Condom

Dear Mr. Pollard:

As discussed in our meeting of October 19, 1993, please accept this letter as a documented, formal request by Apex Medical Technologies, Inc. to have the above-mentioned 510(k) application granted an expedited review. The basis for this request is stated below:

Criteria

Per CDRH's Blue Book Memorandum for Expedited Review dated 6/30/93, criteria #4 provides the basis for this request: Of Specific Health Benefit.

Supporting Argument

The availability of condoms in general are in the best interest of public health, since they can directly reduce the chances of the spread of the HIV virus. During yesterday's discussion, it was apparent that latex condoms were viewed as being safe and effective devices for the prevention of the transmission of the HIV virus. We are in agreement with this. It is also apparent that condom usage is not as widespread as desired for public health purposes, and anything that can be done to increase condom usage should benefit the public health. Accordingly, **only** the polyurethane condom which is the subject of this expedited review combines a higher "load to break" than any currently available latex condom with acceptability by condom users greater than that of regular thickness latex condoms.

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

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Furthermore, latex condoms can be severely weakened by users using oil-based lubricants, such as petroleum jelly, baby oil, mineral oil, etc., whereas the polyurethane condom under review has no such problem. The combination of these advantages may encourage more people to use condoms, and likely reduce HIV transmission rates to some extent. The manufacturing facilities are now in place to begin producing this condom to provide a potential timely public health benefit.

We request that this application for expedited review be given serious consideration. Please call if you have any questions, or need further clarification.

Sincerely,

Mark W. McGlothlin

Mark W. McGlothlin
President

Copies to: Phyliss Barber, LIUSH
Pamela Stratton, M.D. NICHD
William Potter, Ph.D., LIG

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

ODE/DRAERD
REQUEST FOR CONSULTATION

FROM: J. Michael Kuchinski **TO:** Richard Kotz

THROUGH: Colin M. Pollard **THROUGH:** Harry Bushar

510(K) NO. K922688/A Sponsor: Apex Medical Tech. Inc.

DEVICE: Avanti™ "Thick Condom" (Polyurethane) Condom

DESIRED COMPLETION DATE: ASAP

REASON FOR REQUEST

- ☐ NEW SUBMISSION
- [X] RESPONSE TO DEFICIENCY LETTER
- ☐ MODIFIED PROTOCOL
- ☐ MODIFIED DESIGN
- ☐ NEW MATERIALS
- ☐ LABELING
- ☐ MODIFIED MANUFACTURING
- ☐ OTHER Response to a Meeting

TYPE OF REQUEST

- ☐ ENGINEERING REVIEW
- ☐ MATERIALS REVIEW
- ☐ STERILITY REVIEW
- ☐ TOXICOLOGY REVIEW
- ☐ CLINICAL REVIEW
- [X] STATISTICAL REVIEW
- ☐ LABELING REVIEW
- ☐ OTHER REVIEW

COMMENTS/SPECIAL INSTRUCTIONS

(b) (4)

[redacted]

SIGNATURE OF REQUESTER DATE B:\K922688A.CON

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

(b)(4) Test Data

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

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

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Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

Given to CMP 11/3/93 per expedited review guidance

RECEIVED
28 OCT 93 13 46
FDA/CDRH/ODE/DMC

APEX MEDICAL TECHNOLOGIES, INC.
10064 Mesa Ridge Ct. • Suite #202
San Diego, CA 92121
(619) 535-0012 • FAX (619) 535-9715

October 20, 1993

Colin Pollard
Food and Drug Administration
Bureau of Medical Devices
Document Control Center (HFZ - 401)
1390 Piccard Drive
Rockville, MD 20850

Facsimile Number: 1-301-594-2353 2 Pages

Re: REQUEST FOR EXPEDITED REVIEW
510(k) K922688 Polyurethane Condom

Dear Mr. Pollard:

As discussed in our meeting of October 19, 1993, please accept this letter as a documented, formal request by Apex Medical Technologies, Inc. to have the above-mentioned 510(k) application granted an expedited review. The basis for this request is stated below:

Criteria

Per CDRH's Blue Book Memorandum for Expedited Review dated 6/30/93, criteria #4 provides the basis for this request: Of Specific Health Benefit.

Supporting Argument

The availability of condoms in general are in the best interest of public health, since they can directly reduce the chances of the spread of the HIV virus. During yesterday's discussion, it was apparent that latex condoms were viewed as being safe and effective devices for the prevention of the transmission of the HIV virus. We are in agreement with this. It is also apparent that condom usage is not as widespread as desired for public health purposes, and anything that can be done to increase condom usage should benefit the public health. Accordingly, **only** the polyurethane condom which is the subject of this expedited review combines a higher "load to break" than any currently available latex condom with acceptability by condom users greater than that of regular thickness latex condoms.

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

449

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

Furthermore, latex condoms can be severely weakened by users using oil-based lubricants, such as petroleum jelly, baby oil, mineral oil, etc., whereas the polyurethane condom under review has no such problem. The combination of these advantages may encourage more people to use condoms, and likely reduce HIV transmission rates to some extent. The manufacturing facilities are now in place to begin producing this condom to provide a potential timely public health benefit.

We request that this application for expedited review be given serious consideration. Please call if you have any questions, or need further clarification.

Sincerely,

Mark W. McGlothlin

Mark W. McGlothlin
President

Copies to: Phyliss Barber, LIUSH
Pamela Stratton, M.D. NICHD
William Potter, Ph.D., LIG

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

450

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

MEDICAL TECHNOLOGIES, INC.

10064 Mesa Ridge Ct. • Suite #202
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(619) 535-0012 • FAX (619) 535-9715

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

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Mark W. McGlothlin
President

Copies to: Phyliss Barber, LIUSH
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William Potter, Ph.D., LIG

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Memorandum

Date 24 May 1993

From Director
Division of Mechanics and Materials Science HFZ-150

Subject Review of K922688 - Avanti Extra Protection Condom

To Mr J. Michael Kuchinski
ODE/DRAERD HFZ-470

Per your request dated 17 May 1993, I have reviewed the document submitted by Apex Medical Technologies Inc. dated April 6, 1993 in response to the September 2, 1992 letter from Dr. Lillian Yin requesting additional information on the subject 510(k) submission. I reviewed the material and device specifications described in this document in the light of the questions asked in the referenced letter.

1. Device Comparison

The firm shows on Table 1 that an approximate 25 percent increase in strength (force at break) is achieved by a proportional increase in the device thickness. There is no change in either the tensile stress at failure or ultimate elongation of the material. No mechanical/material properties of the device have been degraded by this increase in strength.

2. General Information

a. Appendix A is a table which shows the QA tests, including sampling plan, for the tests used to assure the lot quality of the device. This plan is identical to the plan described in the predicate application.

3. Materials

Apex Medical Technologies certifies that the materials in this device are identical to those in the predicate device.

4. Manufacturing

The firm certifies that all the solvents, compounding additives, etc. are identical to those in the predicate device. The only changes are in the viscosity of the dipping solution and in the dipping profile parameters. In Table 3 the firm provides data to show that the changes in viscosity to not significantly affect the molecular weight of the polymer.

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

5. Material Toxicity

No comment.

6. Finished Product

In addition to the information shown in Appendix G, the information shown on Table 1, discussed above, is relevant. These show that, except for changes which are a direct result of the increased thickness, the final characteristics (dimensions, tensile strength, etc.) have not changed from the predicate product.

7. Quality Assurance

The QA procedures for this device are based on water leak testing, as was the predicate device. The "standard" AQL of 0.4% is used as a QA level.

8. Packaging

No change from the predicate device.

9. Shelf Life

The shelf life for this product will be established in the same manner as the predicate device.

Recommendation: Based on the near identity between this device and the predicate device cleared for market under K902936, this device should be cleared for market.

Donald E. Marlowe

459

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

I N T E R O F F I C E M E M O R A N D U M

Date: 12-May-1993 10:57am DST
From: C. David Lytle
CDL
Dept: OST-DLS
Tel No: 443-7184

TO: John M. Kuchinski (JMK)

CC: Bruce A. Herman (BAH)
CC: W. Howard Cyr (HWC)

Subject: K922688a review

Mike,

Here is my review. I gave you lots of details and a summary that should help with the 2 questions to go back to the manufacturer.

I get the other review done next week.

Cheers, Dave.

455

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

Comments on K922688A - Avanti Thick Condom by Apex Medical Tech.
C.D. Lytle - 5/7/93

This review covers the in vitro "permeability" studies (Barrie
Properties) section of the Amendment.

(b) (4)

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

(b) (4)

[redacted]

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

(b) (4)

[redacted]

SUMMARY: The test data demonstrated that the "thick" PU condom v
as effective as the latex condom as a barrier to virus penetratic
if the following questions can be adequately answered:
1. How much were the pressurized condoms allowed to expand by tl
restrainers? (Were the dimensions reasonable?)
2. Was there loss of viability of the challenge virus inside tl
condom during the test? AND What was the spiking data for tl
other condom types? (Was the loss of virus viability similar, s
that the comparison of condom types is valid?)

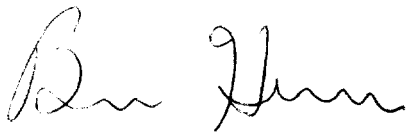
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

Memo

To: Mike Kuchinski, ODE/DRAERD
From: Bruce Herman, OST/DPS
Subject: Review of response to letter of September 2, 1992, re 510K K922688A - Apex Medical Technologies Avanti "Thick Condom"

(b) (4)



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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

ODE/DRAERD
REQUEST FOR CONSULTATION

FROM J. Michael Kuchinski TO Bruce Herman

THROUGH Colin M Pollard CMP 4/27/93 510(K) NO. K922688A

MANUFACTURER Apex Medical Tech. DEVICE Avanti "Thick Condom"

DESIRED COMPLETION DATE May 17, 1993

REASON FOR REQUEST

NEW SUBMISSION	[X]RESPONSE TO DEFICIENCY LETTER
MODIFIED PROTOCOL	MODIFIED DESIGN
NEW MATERIALS	LABELING
MODIFIED MANUFACTURING	OTHER

TYPE OF REQUEST

ENGINEERING REVIEW	MATERIALS REVIEW
STERILITY REVIEW	TOXICOLOGY REVIEW
CLINICAL REVIEW	STATISTICAL REVIEW
LABELING REVIEW	[X]OTHER REVIEW - In-Line QC Barrier

COMMENTS/SPECIAL INSTRUCTIONS

(b) (4)

[redacted]

Please review and comment on the Company's response to the questions raised in our 9/2/92 letter. Any questions, please call at 427-1180 or E-Mail to JMK.

J. Michael Kuchinski

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

ODE/DRAERD
REQUEST FOR CONSULTATION

FROM J. Michael Kuchinski **TO** Donald Marlow

THROUGH Colin M Pollard Cmp 4/23/92 **510(K) NO.** K922688A

MANUFACTURER Apex Medical Tech. **DEVICE** Avanti™ "Thick Condom"

DESIRED COMPLETION DATE May 17, 1993

REASON FOR REQUEST

- ☐ NEW SUBMISSION
- [X] RESPONSE TO DEFICIENCY LETTER
- ☐ MODIFIED PROTOCOL
- ☐ MODIFIED DESIGN
- ☐ NEW MATERIALS
- ☐ LABELING
- ☐ MODIFIED MANUFACTURING
- ☐ OTHER

TYPE OF REQUEST

- ☐ ENGINEERING REVIEW
- [X] MATERIALS REVIEW
- ☐ STERILITY REVIEW
- ☐ TOXICOLOGY REVIEW
- ☐ CLINICAL REVIEW
- ☐ STATISTICAL REVIEW
- ☐ LABELING REVIEW
- ☐ OTHER REVIEW

COMMENTS/SPECIAL INSTRUCTIONS

(b) (4)

[redacted]

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J. Michael Kuchinski /S/

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

4601

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

ODE/DRAERD
REQUEST FOR CONSULTATION

FROM J. Michael Kuchinski **TO** David Lytle

THROUGH Colin M Pollard CMP 9/23/92 **510(K) NO.** K922688A

MANUFACTURER Apex Medical Tech. **DEVICE** Avanti™ "Thick Condom"

DESIRED COMPLETION DATE May 17, 1993

REASON FOR REQUEST

- ☐ NEW SUBMISSION
- [X] RESPONSE TO DEFICIENCY LETTER
- ☐ MODIFIED PROTOCOL
- ☐ MODIFIED DESIGN
- ☐ NEW MATERIALS
- ☐ LABELING
- ☐ MODIFIED MANUFACTURING
- ☐ OTHER

TYPE OF REQUEST

- ☐ ENGINEERING REVIEW
- ☐ MATERIALS REVIEW
- ☐ STERILITY REVIEW
- ☐ TOXICOLOGY REVIEW
- ☐ CLINICAL REVIEW
- ☐ STATISTICAL REVIEW
- ☐ LABELING REVIEW
- [X] OTHER REVIEW - Barrier Properties

COMMENTS/SPECIAL INSTRUCTIONS

(b) (4)

[redacted]

Please review and comment on the Company's response to the questions raised in our 9/2/92 letter. Any questions, please call at 427-1180 or E-Mail to JMK.

J. Michael Kuchinski 15

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

4162

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'EPARTMENT 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

APRIL 9, 1993

APEX MEDICAL TECHNOLOGIES, INC.
ATTN: ALICE A. DEPAUL
10064 MESA RIDGE COURT
SUITE 202
SAN DIEGO, CA 92121

510(k) Number: K922688
Received: 04-07-93
Product: "EXTRA PROTECTION" POLYURETHANE CONDOM

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. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. 'ecause of equipment and personnel limitations we cannot accept telefaxed aterial as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so within 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

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

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

K922688/A

MEDICAL TECHNOLOGIES, INC.

10064 Mesa Ridge Ct. • Suite #202
San Diego, CA 92121
(619) 535-0012 • FAX (619) 535-9715

RECEIVED
7 APR 93 11 13
FDA/CDRH/ODE/DMC

April 6, 1993

Food and Drug Administration
Bureau of Medical Devices
Document Control Center (HFZ - 401)
1390 Piccard Drive
Rockville, MD 20850

Re: K9226888
Avanti ™ "Thick Condom"
(Replacing Avanti ™ Extra Protection Condom)

Dear Sirs/Madam:

This letter is in response to Lillian Yin's letter of September 2, 1992 requesting additional information on the above-referenced 510(k) submission. In light of changes made to our labeling, we have changed our reference for this condom from *Avanti ™ Extra Protection Condom* to *Avanti ™ Thick Condom*. All information contained herein will no longer attempt to justify the label copy claim of "Extra Protection." This condom will simply be a condom which is thicker than the standard thickness condom cleared under premarket notification K902936/A.

The following information corresponds directly with your questions in your letter of September 2, 1992.

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

1. Device Comparison

Table 1: Device Comparison Table

Property	Thick PU Condom	Standard PU Condom	Natural Rubber Latex Condom (ISO - 4074 standard)
Intended Use	Contraception and STD Prevention	Contraception and STD Prevention	Contraception and STD Prevention
Material Composition	Polyurethane	Polyurethane	Natural Latex Rubber
Device Design	Standard Male Condom design, lubricated and rolled with reservoir tip.	Standard Male Condom design, lubricated and rolled with reservoir tip.	Standard Male Condom design, lubricated and rolled with reservoir tip.
Biocompatibility	Excellent, all performed tests indicate acceptability.	Excellent, all performed tests indicate acceptability.	High degree of variability, depending upon raw material source and method of manufacture.
Dimensions (mm)			
Wall Thickness	.045-.050	.035-.040	approx .060
Length	170-185	170-185	approx. 180
Lay-Flat Width body/ring	62-65/52	62-65/52	approx 52/52
Manufacturing Process	dip molded process, solvent based	dip molded process, solvent based	dip molded process, emulsion based.
Physical Specs			
Tensile Strength (MPa)	Min. 55	Min. 55	17 (minimum)
Ult. Elong. (%)	Min. 500	Min. 500	650 (minimum)
Force at Break (newtons)	Min. 100	Min. 80	34 (minimum)
Air Burst Pressure (KPa)	Min. 4.0	Min. 3.5	1.0 (minimum)
Air Burst Volume (liters)	Min. 9	Min 7	15 (minimum)

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

465

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

2. General Information

a. The quality plan in Appendix A provides a detailed description of the test procedures used by the manufacturer to establish the quality of each condom lot or batch, and additionally, identifies when quality control tests are conducted during the manufacturing process.

b. Revised label copy for the thick condom is provided in Appendix B. The user trial which was performed to determine breakage and slippage rates for this condom, report RPRT 451 (report attached in Appendix C) also incorporated user preference information. At the end of the trial, participants were asked to rate the test condoms out of a maximum score of 10, on a number of subjective parameters. The results form the basis for the pack statements that the PU condom is sensitive, natural feeling, clear and has no odor. The results are reported in Table II below. In all instances, the PU condom was rated more highly than the natural rubber (latex) condom, however none of the statements on the pack are comparative - they are only direct descriptions of the PU condom's attributes. The one issue not directly asked of users was that of clarity. However, if the unrolled, lubricated condom is placed on a page of print, then the print is completely readable through the condom.

Table 2: Subjective Evaluation of PU and Natural Rubber (NR) Latex Condoms

Property	PU Condom	NR Condom
Sensitivity	6.0	5.6
Feels Natural	5.6	5.0
Looks Natural	5.9	5.7
Lack of Smell	7.0	6.2
Appearance	5.9	5.6

Note: Scores are averages out of 10 (n=187 for NR, n=199 for PU)

3. Materials

Apex Medical Technologies certifies that the raw material(s) specifications (chemical and physical) and material(s) suppliers being used for the thick condom are identical to those used for the standard thickness polyurethane condom. This includes:

1. the molar ratio for component monomers

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

2. the specification for raw materials and the quality control testing performed

3. the chemical composition and physical specifications of the raw material(polyurethane) including molecular weight and molecular weight distribution; and

4. quantities of residual monomer (urethane) and any additives or by-products.

4. Manufacturing

(b) (4)

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

(b) (4)

[redacted]

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

468

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

5. Material Toxicity

(b) (4)

[redacted]

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

(b) (4)

[redacted]

7. Quality Assurance

(b) (4)

[redacted]

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

910

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

8. Packaging

Apex Medical Technologies, Inc. certifies that the packaging material specification for this thicker condom is the same as that used for the standard thickness polyurethane condom.

9. Shelf Life

Shelf life testing will be conducted in an identical manner as described for the standard thickness condom, cleared in premarket notification # K902936/A., which was stated as follows:

In order to further establish the stability of the polyurethane condom, a long term program which will monitor the stability of the polyurethane condoms over time will be conducted. This program will follow the outline below:

LONG TERM STABILITY

- *A statistically significant number of sample condoms taken from each of the first three production lots are to be put into a long term stability test program.*
- *Sample condoms will be held at 4° Celsius , room temperature, and 40° Celsius and tested at the following intervals: Initial, 1 month, 2 months, 3 months, 6 months, 1 year, 2 years, 3 years, and 5 years.*
- *Tensile strength, elongation at break, and load to break values will be measured at each cell. Values will be established by procedures referred to in ASTM 3492.*
- *Data will be monitored for significant changes in the polyurethane condoms. When a change occurs, the data will be analyzed using the standard Arrhenius technique to predict shelf life. Reference: Anderson et al, Remington's Pharmaceutical Sciences, 15th Edition, page 1424 to 1426.*

The initial shelf life testing of the standard thickness condom showed no problems. Because of the identical materials of construction, this thicker condom should show no differences in aging.

10. Permeability

Although we now have removed the extra protection claim from our label copy, we have performed the in-vitro permeability studies and can demonstrate that the thicker condom is an improved barrier relative to latex rubber condoms with respect to sexually transmitted diseases of appropriate size.

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

The barrier properties of the PU condoms and NR (latex) condoms were evaluated according to the methodology developed through discussions between London International U.S. Holdings and the Office of Device Evaluation. In essence, the condoms were challenged with a suspension of a bacteriophage, (particle size=27 nm), under conditions simulating those experienced during coitus. Testing was carried out by Nelson Laboratories according to the protocol 912171-3. This protocol is attached in Appendix H. 20 condoms of each type were tested - the predicate PU condom (single wall thickness of circa 30 microns), the present PU condom (single wall thickness of circa 45 microns), and the best selling NR condom, Trojan Enz (single wall thickness of circa 60 microns). Under the conditions of the test, the 35 micron PU condom showed passage of the phage in four instances, the 45 micron PU condom in five instances and the 60 micron NR condom in 8 instances. This demonstrates the improved barrier properties of the PU condoms over those of the best selling regular NR condom. The data for the test condoms that showed passage of the phage during or at the end of the test, are summarized in the table which is also found in Appendix H. Data for condoms showing no passage of the phage are not included.

11. Clinical Data

A clinical user study has been performed incorporating the thicker PU condom, in order to demonstrate the performance of this device during use. Breakage rate and slippage rate data were recorded versus that from a regular NR (Natural Rubber latex) condom. The results are summarized in the report (RPRT 451 "Summary of the Effect of the Material and Design Changes on the Breakage and Slippage rates of Apex Condoms") in Appendix C. No significant differences were found between the breakage or slippage levels of the thicker PU condom when compared to those of a standard Natural Rubber latex condom.

12. Device Labeling

In response to your labeling concerns on the use of the phrase "extra protection", we have chosen to omit this claim from our labeling. Our proposed current labeling (found in Appendix B) now makes three justifiable claims: 1) twice as strong as latex, 2) thinner than regular condoms, and 3) twice as strong as the best selling condom. The data provided in Table I and Table II of the first submission for this 510(k), dated May 29, 1992, fully substantiates these claims. Please note that Trojan Enz condoms have 70% U.S. market share for the regular condom market, and accordingly, were used as the comparative latex rubber condoms in this testing.

An updated Summary of this 510(k) is contained in Appendix I.

We consider our intent to market this thicker polyurethane condom confidential commercial information, and request that this information be considered as such by the

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

FDA. Additionally, some details contained in this letter are confidential in nature. We request the removal of the proprietary details of this submission from any potential disclosure under the Freedom of Information Act.

Should you require further information relating to this amendment, please contact me at (619) 535-0165.

Sincerely,

Alice A. DePaul

Alice A. DePaul
Vice President

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

Appendix A

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

(b)(4) Test Data

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

Appendix B

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

FRONT

New Material Technology

Technologically advanced Duron™ condom protection. Provides a unique combination of sensitivity and strength with protection against pregnancy and sexually transmitted diseases

Non-allergenic, clear, odorless

Thinner than regular condoms

Duron™ : A technologically advanced material that is twice as strong as latex. Duron™ condoms can be made much thinner than regular condoms to provide a unique combination of sensitivity and protection.

Avanti™
Duron™ Condoms

Twice as strong as the best selling condom

Lubricated Condoms

(Net contents statement, as required by the Fair Packaging and Labeling Act).

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

REVERSE

Avanti™ Condoms are made from Duron, a technologically advanced material which has allowed us to make them twice as strong as the best selling condom yet thinner than regular condoms.

Proper Use of Avanti Condoms

Avanti™ Condoms, when properly used, are highly effective against pregnancy -- although no contraceptive can guarantee 100% effectiveness. Any use of Avanti condoms for other than vaginal intercourse can increase the potential of damage to the condom. Avanti Condoms, when properly used, may help reduce the risk of catching or spreading Sexually Transmitted Diseases ("STD's") such as syphilis, gonorrhea, chlamydia infections, genital herpes and AIDS, however, it cannot eliminate the risk.

For maximum benefits, it is important to follow the instructions for use included with 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 STD's. Therefore, the condom should be applied each and every time before any such contact occurs.

Storage: Avoid prolonged storage of condoms at temperatures in excess of 100 degrees Fahrenheit -- storage for short period of time at this temperature will not be harmful to the product. Avoid any storage close to a hot radiator, hot air duct or similar object.

Distributed by: SCHMID LABORATORIES, DIVISION OF LONDON INTERNATIONAL U.S. HOLDINGS, INC., SARASOTA, FLORIDA 34230-4703.

(Labeling of date of manufacture.)

(Country of origin statement in compliance with Customs and Federal Trade Commission Regulations).

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

Appendix C

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

(b)(4) Test Data

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

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

(b)(4) Test Data

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

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

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

Appendix D

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

CONDOM PRODUCTION FLOW DIAGRAM

(b) (4)

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

Appendix E

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

(b)(4) Test Data

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

Appendix F

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

(b) (4)

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

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

(b) (4)

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

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

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

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

(b) (4)

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

Appendix G

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

PRODUCT SPECIFICATION - AVANTI CONDOM

PRODUCT TYPE:

CHARACTERISTICS:

(b) (4)

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

SDL

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

Appendix H

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

505

(b)(4) Test Data

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

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

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Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

Appendix I

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

510(k) Summary
Statement of Safety and Effectiveness

I.	**Submitter's Name:**	Apex Medical Technologies, Inc. 10064 Mesa Ridge Court, Suite 202 San Diego, CA 92121
II.	**Submitter's Phone Number:**	(619) 535-0012
III.	**Contact Person:**	Alice A. DePaul, Vice President
IV.	**Date of Preparation:**	January 27, 1993
V.	**Name of Device:**	"Polyurethane Condom"
VI.	**Trade or Proprietary Name:**	"Avanti Condom"
VII.	**Common or Usual Name:**	Condom
VIII.	**Classification Name:**	Condom
IX.	**Predicate or legally marketed device or devices to which substantial equivalence is claimed:**	Currently marketed latex condoms and the polyurethane condom described in 510(k) Premarket notification # K902936/A, accepted by FDA on March 6, 1991.

X. General Description of the diseases or conditions the device will diagnose, treat,prevent, cure or mitigate, including a description of the patient population for which the device in intended:

This condom is intended to aid in the prevention of pregnancy, and is intended to help prevent the transmission of sexually transmitted diseases. The patient population for which this product is intended is as follows: people who engage in vaginal intercourse who wish to reduce the likelihood of becoming pregnant and/or contracting sexually transmitted disease(es). This condom is not intended for people who expect absolute protection. People requiring absolute protection from pregnancy and/or sexually transmitted diseases should consult their physicians for alternatives.

XI. Description of Device:

This polyurethane condom is a combination contraceptive and disease prevention device which functions by acting as a barrier to the transfer of semen and/or infective microorganisms known to cause sexually transmitted diseases. This barrier protection is intended to be effective for vaginal intercourse only. The basis for function of this device is based upon the fact that these condoms are essentially pore-free and will not allow for the passage of spermatozoa or disease organisms between sexual partners during vaginal intercourse.

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

The main cylindrical portion of this condom is produced from a material called polyurethane. The open end of the condom has a ring made from a proprietary synthetic rubber material which is softer than the polyurethane to provide for added comfort to the user.

XII. Description of Non-Clinical Tests and Their Results

The results of physical properties testing support the substantial equivalency claims. The results of the physical properties tests show the polyurethane condoms to have higher tensile strengths, and air burst pressures than currently marketed latex condoms. Average air burst pressure for this polyurethane condom was shown to be 5.50 kilopascals, compared to 1.34 kilopascals for standard thickness latex condoms and 1.72 kilopascals for extra strength latex condoms. The average tensile strength for this polyurethane condom was shown to be 61.0 megapascals, compared to 20.32 megapascals for standard thickness latex condoms and 25.08 megapascals for extra strength latex condoms.

The release criteria for this condom is based upon the water leakage test described in ASTM Standard Specification for Rubber Contraceptives (Condoms) D 3492 and will be set to a level of AQL=0.4 General Inspection Level I, (Mil/Ansi Spec 105), compared to AQL=0.4 General Inspection Level I, (Mil/Ansi Spec 105) for standard latex condoms and extra strength latex condoms.

XIII. Conclusions drawn from nonclinical and clinical tests that demonstrate the device is "safe, effective and performs as well or better than the currently legally marketed device".

Based upon superior physical properties, and based upon product release criteria, this condom is expected to be substantially equivalent or superior to currently marketed latex condoms.

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

SSP

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

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

OCTOBER 5, 1992

APEX MEDICAL TECHNOLOGIES, INC.
ATTN: ALICE A. DEPAUL
10064 MESA RIDGE COURT
SUITE 202
SAN DIEGO, CA 92121

510(k) Number: K922688
Product: "EXTRA PROTECTION" POLYURETHANE CONDOM

Extended Until: 01/02/93

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information is not received by the "Extended Until" date shown above your premarket notification will be considered withdrawn.

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

Sincerely yours,

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

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

S10

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

APEX MEDICAL TECHNOLOGIES, INC.

10064 Mesa Ridge Ct. • Suite #202
San Diego, CA 92121
(619) 535-0012 • FAX (619) 535-9715

September 28, 1992

Food and Drug Administration
Bureau of Medical Devices
Document Control Center (HFZ - 401)
1390 Piccard Drive
Rockville, MD 20850

RECEIVED
29 SEP 92 13 17
FDA/CDRH/OCE/DMC

Re: 510(k) File Number K922688 Extra Protection Condom

Dear Sirs/Madam:

The intent herein is to document a verbal confirmation with Barbara Jackson of the Document Control Center on September 28, 1992 of a 90 day extension on the Apex response to an FDA letter dated September 2, 1992 referencing the above named file. Please alter your records as necessary to reflect this 90 day extension of our response to the requested information to January 2, 1993.

If there are any further question, or if this does not meet with your approval, please contact Alice DePaul at (619) 535-0012.

Sincerely,

Alice A. DePaul

Alice A. DePaul
Vice President

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

SEP 2 1992

Ms. Alice A. DePaul
Vice President
Apex Medical Technologies, Inc.
10064 Mesa Ridge Court
Suite 202
San Diego, California 92121

Re: K922688
Avanti™ Extra Protection Condom
Dated: May 29, 1992
Received: June 4, 1992

Dear Ms. DePaul:

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.

We acknowledge that this device, for purposes of demonstrating substantial equivalence, is to be compared to your polyurethane condom cleared in K902936/A. We also acknowledge that much of the data included in your previous 510(k) may be used to support a substantial equivalence determination in terms of safety and effectiveness for this new device. Nevertheless, in order for us to complete the review of your submission, we require the following information or appropriate scientific justification in lieu of a complete response to the questions below:

1. Device Comparison

   Compare your device, in tabular form, to a legally marketed device, particularly your standard thickness polyurethane condom as well as a latex condom. This comparison should include, but should not be limited to, the intended use, material composition, device design, biocompatibility, dimensions, manufacturing process, physical specification, e.g., elongation.

2. General Information

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

   b. Provide copies of labels, labeling and advertisements sufficient to describe the device directions for use. In addition, please be advised that statements that refer to qualitative properties of the device, i.e., "Clear and Sensitive", "Natural Feeling", and "No

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

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Odor", will need to be substantiated with data or must be deleted from the labeling.

3. Materials

a. Provide evidence that the raw material(s) specifications (chemical and physical) and material suppliers are identical to those used for the standard thickness polyurethane condom, or provide a detailed description of the materials which should include:

1. molar ratio of component monomers for fabricating the material;

2. specifications for the raw materials and a description of the quality control testing performed;

3. chemical composition and physical specifications of the raw material (polyurethane) including molecular weight and molecular weight distribution; and

4. quantities of residual monomer (urethane) and any additives or by-products.

4. Manufacturing

a. Provide certification that the manufacturing processes have not changed from that used for the standard thickness polyurethane condom, or provide a detailed description of the change in the manufacturing processes to include the following:

1. flow diagram;

2. solvent(s);

3. compounding additives including any color additive that may be added (If a color additive is used, provide its chemical composition, and identify the color index number and reference the specific color additive listing (21 CFR reference));

4. solution handling processes;

5. batch sizes of both the undissolved and dissolved dipping mixture;

6. filtration of the stock materials;

7. process control parameters, such as solution viscosity and temperature, system metrology, air handling specifications, particulate control, packaging process; and

8. the handling and/or reworking procedures of the product that fail any of the in-process quality control tests.

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

b. Provide data to ensure that the change in the manufacturing processes will not alter the molecular weight and molecular weight distribution of the material.

c. Provide data on the quantities of residual solvent(s) and additives in condoms.

5. Material Toxicity

a. Provide toxicity data on all the monomers, additives, and solvents utilized in manufacturing of the material(s) of the condom if different from the standard thickness polyurethane condom.

b. Provide toxicity data on dusting agents and lubricants if different from the standard thickness polyurethane condom.

c. Provide biocompatibility data on the final product demonstrating that the condom does not produce acute and chronic toxicity, including mucosal irritation and sensitization.

6. Finished Product

a. Provide the device physical specifications including the length, width, and mass.

b. Provide data from the following mechanical tests conducted on the final product:

1. elongation;

2. tear resistance and propagation;

3. air burst volume;

4. water leakage.

c. Provide data to demonstrate that the product's physical integrity is not compromised at body temperature, (i.e., force at break, tensile strength and elongation at 37°C).

7. Quality Assurance

a. Provide a detailed description of the test procedures, if different from the standard thickness polyurethane condom, used by the manufacturer to establish the quality of each condom lot or batch, including:

1. when testing is performed during the manufacturing processes;

2. a detailed description of any in process testing procedures including a description of the in process testing machine, the

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

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machine's specifications, and operator's manual and a description of the testing machine's calibration procedures;

3. data to demonstrate the sensitivity of the in process testing machine;

4. a description of the relationship between the in process testing machines' calibration procedures to the product release testing procedures; and

5. the acceptable quality level (AQL), for dimensions, color fastness, and physical requirements, its meaning, and the sampling procedure and the inspection level used to achieve the desired AQL.

8. Packaging

Provide a description of the package material specification if different from that used for the standard thickness polyurethane condom.

9. Shelf-Life

Provide real-time and accelerated data to substantiate the shelf-life of the device, including an analysis for chemical degradation and mechanical properties over time under ideal conditions of temperature and humidity. The data should include a statistically valid sample size.

10. Permeability

Provide data from *in vitro* permeability studies to demonstrate the improved barrier properties of the Avanti™ Extra Protection polyurethane condom, compared to your predicate polyurethane condom and latex condoms, with respect to sexually transmitted diseases (STDs) of appropriate size. Test methodology must simulate actual use.

11. Clinical Data

Provide the results from a clinical study with a statistically valid sample size, to demonstrate the performance of the devices during use. This should include the breakage rate of the condoms during use, the slippage rate of the condoms during use and any adverse reactions experienced by study subjects.

12. Device Labeling

Please be advised that FDA considers use of the phrase "Extra Protection" in your trade name may be misleading. That the phrase may lead consumers to believe that your condom offers superior protection against the transmission of the sexually transmitted diseases including the HIV virus responsible for Acquired Immune Deficiency Syndrome (AIDS). Justify your

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

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product name or change it to one that simply reflects its improved physical characteristics.

Please be advised that FDA will not permit any claims, explicit or implied, that your condom is "Allergy Free" or hypoallergenic. Also, please be advised that in accordance with Section 304 of the United States Tariff Act, every retail package of foreign origin entering the United States must be legibly marked (outer box) with the English name of the country of origin. The marking must be legible and in a conspicuous place on the package. For further information, contact your local custom's office.

The additional information should be submitted in duplicate, referencing the 510(k) number above to:

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

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

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(f) and (h), and you have received a letter from FDA allowing you to do so. 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.

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 Mr. J. Michael Kuchinski at (301) 427-1180. If you need information or assistance concerning the IDE regulations, please contact the Division of

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

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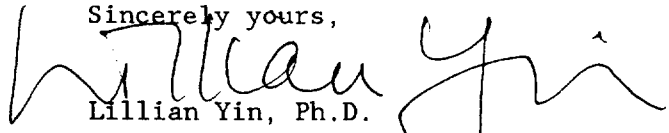
Small Manufacturers Assistance at their toll free number 1-800-628-2041 or at (301) 443-6597.

Sincerely yours,



Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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

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DO NOT REMOVE THIS ROUTE SLIP!!!!

K-92-2688 9/3/92

FROM:	LETTER DATE	LOGIN DATE	DUE DATE
APEX MEDICAL TECHNOLOGIES, INC. ATTN: ALICE A. DEPAUL 10064 MESA RIDGE COURT SUITE 202 SAN DIEGO, CA 92121	05/29/92	06/04/92	09/02/92
	TYPE OF DOCUMENT: 510 (k)		CONTROL # K922688
SHORT NAME: APEXMEDITECH	PHONE NO: 619-535-0012 ESTABLISHMENT NO: 1045600		

TO:	
ODE/DMC	CONT. CONF.: ? STATUS : H REV PANEL : OB PAN/PROD CODE(S): OB/ / /

SUBJECT:
"EXTRA PROTECTION" POLYURETHANE CONDOM

DECISION:	RQST INFO DATE: 09/03/92	INFO DUE DATE: 10/03/92
DECISION DATE: / /	DATE: / /	DATE: / /
	DATE: / /	DATE: / /
	DATE: / /	DATE: / /
	DATE: / /	DATE: / /
	DATE: / /	DATE: / /

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

SEP 2 1992

Ms. Alice A. DePaul
Vice President
Apex Medical Technologies, Inc.
10064 Mesa Ridge Court
Suite 202
San Diego, California 92121

Re: K922688
Avanti™ Extra Protection Condom
Dated: May 29, 1992
Received: June 4, 1992

Dear Ms. DePaul:

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.

We acknowledge that this device, for purposes of demonstrating substantial equivalence, is to be compared to your polyurethane condom cleared in K902936/A. We also acknowledge that much of the data included in your previous 510(k) may be used to support a substantial equivalence determination in terms of safety and effectiveness for this new device. Nevertheless, in order for us to complete the review of your submission, we require the following information or appropriate scientific justification in lieu of a complete response to the questions below:

1. Device Comparison

   Compare your device, in tabular form, to a legally marketed device, particularly your standard thickness polyurethane condom as well as a latex condom. This comparison should include, but should not be limited to, the intended use, material composition, device design, biocompatibility, dimensions, manufacturing process, physical specification, e.g., elongation.

2. General Information

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

   b. Provide copies of labels, labeling and advertisements sufficient to describe the device directions for use. In addition, please be advised that statements that refer to qualitative properties of the device, i.e., "Clear and Sensitive", "Natural Feeling", and "No

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

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Odor", will need to be substantiated with data or must be deleted from the labeling.

3. Materials

a. Provide evidence that the raw material(s) specifications (chemical and physical) and material suppliers are identical to those used for the standard thickness polyurethane condom, or provide a detailed description of the materials which should include:

1. molar ratio of component monomers for fabricating the material;

2. specifications for the raw materials and a description of the quality control testing performed;

3. chemical composition and physical specifications of the raw material (polyurethane) including molecular weight and molecular weight distribution; and

4. quantities of residual monomer (urethane) and any additives or by-products.

4. Manufacturing

a. Provide certification that the manufacturing processes have not changed from that used for the standard thickness polyurethane condom, or provide a detailed description of the change in the manufacturing processes to include the following:

1. flow diagram;

2. solvent(s);

3. compounding additives including any color additive that may be added (If a color additive is used, provide its chemical composition, and identify the color index number and reference the specific color additive listing (21 CFR reference));

4. solution handling processes;

5. batch sizes of both the undissolved and dissolved dipping mixture;

6. filtration of the stock materials;

7. process control parameters, such as solution viscosity and temperature, system metrology, air handling specifications, particulate control, packaging process; and

8. the handling and/or reworking procedures of the product that fail any of the in-process quality control tests.

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

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b. Provide data to ensure that the change in the manufacturing processes will not alter the molecular weight and molecular weight distribution of the material.

c. Provide data on the quantities of residual solvent(s) and additives in condoms.

5. Material Toxicity

a. Provide toxicity data on all the monomers, additives, and solvents utilized in manufacturing of the material(s) of the condom if different from the standard thickness polyurethane condom.

b. Provide toxicity data on dusting agents and lubricants if different from the standard thickness polyurethane condom.

c. Provide biocompatibility data on the final product demonstrating that the condom does not produce acute and chronic toxicity, including mucosal irritation and sensitization.

6. Finished Product

a. Provide the device physical specifications including the length, width, and mass.

b. Provide data from the following mechanical tests conducted on the final product:

1. elongation;

2. tear resistance and propagation;

3. air burst volume;

4. water leakage.

c. Provide data to demonstrate that the product's physical integrity is not compromised at body temperature, (i.e., force at break, tensile strength and elongation at 37°C).

7. Quality Assurance

a. Provide a detailed description of the test procedures, if different from the standard thickness polyurethane condom, used by the manufacturer to establish the quality of each condom lot or batch, including:

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SSI

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machine's specifications, and operator's manual and a description of the testing machine's calibration procedures;

3. data to demonstrate the sensitivity of the in process testing machine;

4. a description of the relationship between the in process testing machines' calibration procedures to the product release testing procedures; and

5. the acceptable quality level (AQL), for dimensions, color fastness, and physical requirements, its meaning, and the sampling procedure and the inspection level used to achieve the desired AQL.

8. Packaging

Provide a description of the package material specification if different from that used for the standard thickness polyurethane condom.

9. Shelf-Life

Provide real-time and accelerated data to substantiate the shelf-life of the device, including an analysis for chemical degradation and mechanical properties over time under ideal conditions of temperature and humidity. The data should include a statistically valid sample size.

10. Permeability

Provide data from *in vitro* permeability studies to demonstrate the improved barrier properties of the Avanti™ Extra Protection polyurethane condom, compared to your predicate polyurethane condom and latex condoms, with respect to sexually transmitted diseases (STDs) of appropriate size. Test methodology must simulate actual use.

11. Clinical Data

Provide the results from a clinical study with a statistically valid sample size, to demonstrate the performance of the devices during use. This should include the breakage rate of the condoms during use, the slippage rate of the condoms during use and any adverse reactions experienced by study subjects.

12. Device Labeling

Please be advised that FDA considers use of the phrase "Extra Protection" in your trade name may be misleading. That the phrase may lead consumers to believe that your condom offers superior protection against the transmission of the sexually transmitted diseases including the HIV virus responsible for Acquired Immune Deficiency Syndrome (AIDS). Justify your

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product name or change it to one that simply reflects its improved physical characteristics.

Please be advised that FDA will not permit any claims, explicit or implied, that your condom is "Allergy Free" or hypoallergenic. Also, please be advised that in accordance with Section 304 of the United States Tariff Act, every retail package of foreign origin entering the United States must be legibly marked (outer box) with the English name of the country of origin. The marking must be legible and in a conspicuous place on the package. For further information, contact your local custom's office.

The additional information should be submitted in duplicate, referencing the 510(k) number above to:

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Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

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

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

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Small Manufacturers Assistance at their toll free number 1-800-628-2041 or at (301) 443-6597.

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

cc: HFZ-401
HFZ-470
DO

JMKuchinski
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Draft: 08/31/92:jmk
Final: 09/02/92:jmk

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
Z470	Kuchinski	9/2/92						
Z-470	Tsu	9/2/92						

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

☆ U.S. GOVERNMENT PRINTING OFFICE : 521-49

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DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Memorandum

Date

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

Subject 510(k) NOTIFICATION K922688

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:

Is this device subject to Postmarket Surveillance? Yes ☐ No ☐

This 510(k) contains: (check appropriate box(es))

☑ A 510(k) summary of safety and effectiveness, or

☐ A 510(k) statement that safety and effectiveness information will be made available

☐ The required certification and summary for class III devices

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: MRT for Colin Pollard (BRANCH CHIEF) — OGDB (BRANCH CODE) — 9/11/92 (DATE)

FINAL REVIEW: [signature] (DIVISION DIRECTOR) — 9/2/92 (DATE)

*DOES NOT APPLY TO ANY 510 DECISIONS

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

SSS

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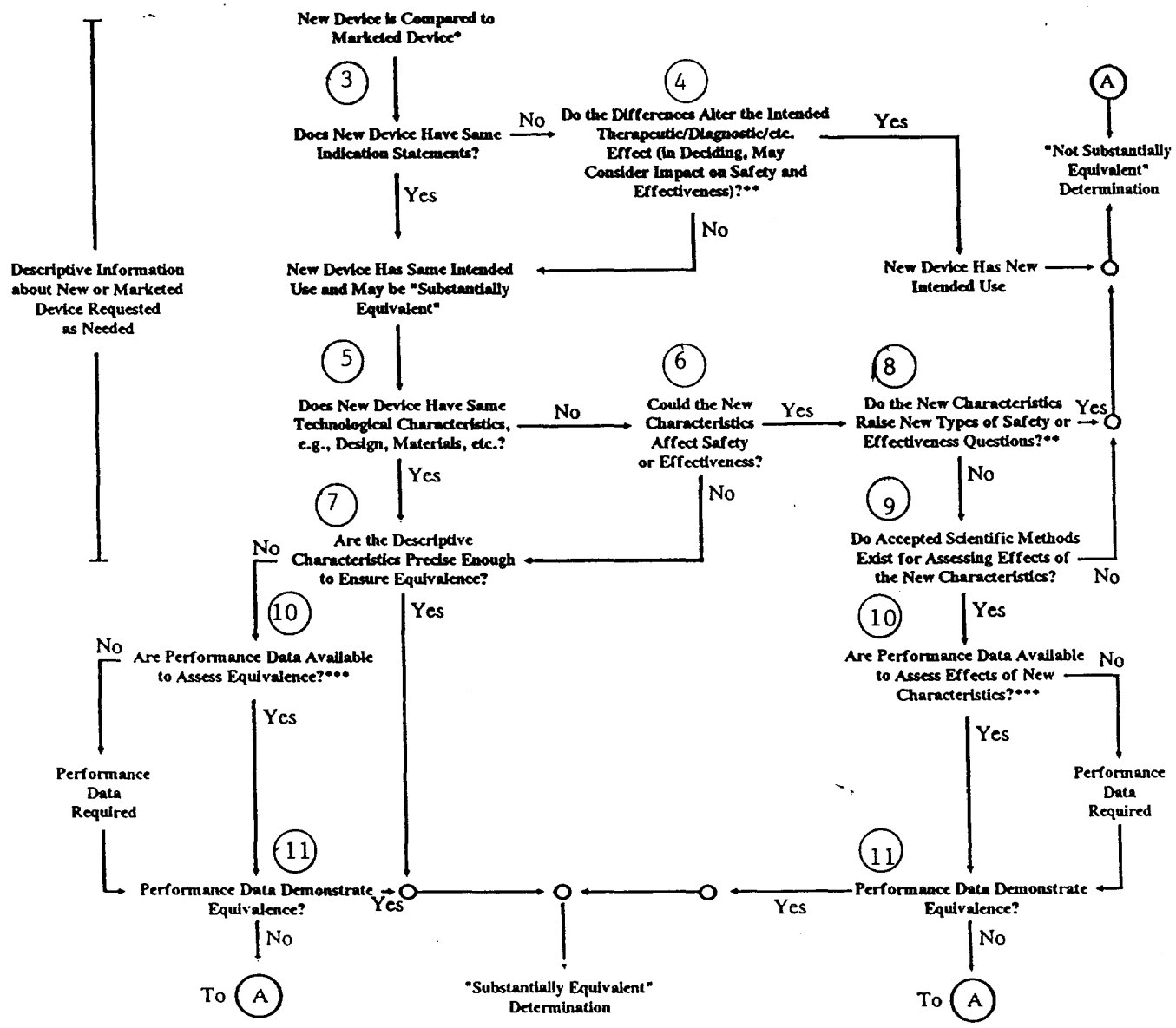
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS (DETAILED)



* 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.

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

K922688

Reviewer: J. Michael Kuchinski
Microbiologist

Division/Branch: DRAERD/Ob-Gyn (HFZ-470)

Proprietary Trade Name: Avanti Extra Protection Condoms

Common Name: Condom, Polyurethane Condom, 21 CFR §884.5300

Product to which compared: Polyurethane Condom, K902936

Applicant: Apex Medical Technologies, Inc.
10064 Mesa Ridge Court
Suite 202
San Diego, California 92121

Contact: Ms. Alice DePaul
Vice President

Phone: (619) 535-0012

NARRATIVE DEVICE DESCRIPTION

It is the intention of the manufacturer, Apex Medical Technologies, Inc., to market a device, "extra protection" polyurethane condom under the trade name "Avanti Extra Protection Condoms".

The applicant has identified that this device is equivalent to the polyurethane condom found substantially equivalent, March 6, 1991, under K902936/A. The applicant also claims equivalence to the Lifestyles Extra Strength Condoms (Ansell) and to Trojan-Enz with Special Receptacle End (Carter-Wallace).

The device is a condom identified by the applicant as being identical in all but three aspects from that of the "standard thickness polyurethane condom" (identified above.). The differences include:

- The nominal single wall thickness specification of the "Avanti Extra Protection Condoms" is 0.045 mm compared to 0.03 mm for the "standard thickness polyurethane condom".
- The proposed Acceptable Quality Level (AQL) for the "Avanti Extra Protection Condoms" for water leakage is to be 0.25 compared to 0.4 for the "standard thickness polyurethane condom".
- The labeling has changed to identify the condom as "Extra Protection", and to reflect the changes in the points above, thicker and increased QA levels.

The applicant has identified that this device is to be commercialized in combination with London International Group, plc, (parent company of Schmid Laboratories division of London International U.S. Holdings, Inc.). Initial location of the manufacturing site is to be Cambridge, ENGLAND, with subsequent manufacturing to be located in Anderson, South Carolina.

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

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

1. Intended Use:

This device draft labeling identifies the condom as "Superior Non-Latex Condom", "Technologically Advanced Condoms", "New Avanti Extra Protection Condoms". Additional claims include "Clear and Sensitive", "Natural Feeling", "No Odor", and "Allergy Free".

The rear panel provides the specific indications for use that include: "...when properly used, are highly effective against pregnancy -- although no contraceptive can guarantee 100% effectiveness.", and "...when properly used, may help reduce the risk of catching or spreading Sexually Transmitted Diseases ("STD's") such as syphilis, gonorrhea, chlamydia infections, genital herpes and AIDS, however, it cannot eliminate the risk.". Thus the device is indicated for contraception and as an aid to the prevention of sexually transmitted diseases (STDs).

This application does not include any labeling directions for use. The applicant should be requested to provide copies of labels, and labeling sufficient to describe the device directions for use.

2. Device Description:

A complete description of the device is not presented in this application. The applicant refers to K902936/A for a complete description of the device.

This application includes a statement that the manufacturing procedures "...will be very similar to that used for the standard thickness condom described in the previous 510(k). A process change that 1) uses a different dipping rate and 2) uses a higher percent solids dipping solution will be used to achieve the desired wall thickness. No other process changes are planned." These changes in the manufacturing process are the basis for requesting additional information to verify that the device is substantially equivalent to the "standard thickness" polyurethane condom (K902936/A).

The application includes comparative data from tensile strength testing and air burst testing comparing the "Extra Protection" Polyurethane Condom to the Standard Thickness Polyurethane Condom and to 2 latex condoms, "Trojan-Enz" and "Lifestyles Extra Strength". The following data has been presented:

	Thickness (mm)	Peak Load (N)	Tensile Strength (MPa)	Burst Pressure (kPa)
Extra Protection Condom	0.042-0.045	110.9	61.0	5.5
Standard Polyurethane Condom	0.028-0.035	86.1	60.8	3.88
Trojan-Enz	0.058-0.061	47.5	20.32	1.34
Extra Strength Lifestyles	0.082-0.105	105.23	25.08	1.72

This information indicates that the device does offer an increase in the strength properties of the device but do not substantiate the claim of "Extra Protection", which is a claim of clinical utility not strength. In other words the argument is that the increases in strength offer increases in the protective effect of this device for contraception and for transmission of STDs including AIDS.

Significant questions have not been addressed pursuant to the guidance, REQUIRED INFORMATION FOR A 510(k) SUBMISSION FOR A NON-LATEX CONDOM, May 10, 1991.

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

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	YES	NO
• Is the device life-supporting or life sustaining?	___	X
• Is the device implanted (**short-term** or long-term)?	X	___
• Does the device design use software?	___	X
• Is the device sterile?	___	X
• Is the device single use?	X	___
• Is the device home use?	X	___
• Is the device for prescription?	___	X
• Does the device contain a drug or biological product as a component?	___	X
• Is this device a kit?	___	X

The following questions need to be addressed by the applicant in order for review to continue:

Miin-Rong Tsai, Ph.D. was consulted regarding this application and the proposed changes in the manufacture of the device. In his opinion the increase in the thickness in the device membrane could have an affect on the amount of residual solvent within the device membrane (toxicity). In addition, the change in the dipping process and the dipping solution may have necessitated changes in the manufacturing process itself that could have an affect on the final product. MRT 9/1/92

Note: The following questions are extracted from the guidance, identified above, with modifications that would allow for the applicant to certify that the device parameters (e.g., manufacturing change, material change, supplier change, etc.) have or have not changed from the device found SE under the 510K K902936/A, the standard thickness polyurethane condom.

1. Device Comparison

Compare your device, in tabular form, to a legally marketed device. This comparison should include, but should not be limited to, the intended use, material composition, device design, biocompatibility, dimensions, manufacturing process, physical specification, e.g., tensile strength, elongation, force at break, etc.

2. General Information

a. Provide a detailed description of the test procedures used by the manufacturer to establish the quality of each condom lot of batch. Additionally, identify when quality control tests are conducted during the manufacturing process.

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

SSP

Records processed under FOIA Request # 2015-1976; Released by CDRH on 09-03-2015

b. Provide copies of labels, labeling and advertisements sufficient to describe the device directions for use. In addition, please be advised that statements that refer to qualitative properties of the device, i.e., "Clear and Sensitive", "Natural Feeling", and "No Odor", will need to be substantiated with data or must be deleted from the labeling.

3. Materials

a. Provide evidence that the raw materials specification (chemical and physical) and material suppliers are identical to those used for the standard thickness polyurethane condom, or provide a detailed description of the materials which should include:

1. molar ratio of component monomers for fabricating the material;

2. specification for the raw materials and a description of the quality control testing performed;

3. chemical composition and physical specifications of the material including molecular weight and molecular weight distribution; and

4. quantities of residual monomers and additives.

4. Manufacturing

a. Provide certification that the change in the manufacturing processes have not changed from that used for the standard thickness polyurethane condom or provide a detailed description of the condom manufacturing processes to include the following:

1. flow diagram;

2. solvent(s);

3. compounding additives including any color additive that may be added (If a color additive is used, provide its chemical composition, and identify the color index number and reference the specific color additive listing (21 CFR reference));

4. solution handling processes;

5. batch sizes of both the undissolved and dissolved dipping mixture;

6. filtration of the stock materials;

7. process control parameters, such as solution viscosity and temperature, system metrology, air handling specifications, particulate control, packaging process; and

8. the handling and/or reworking procedures of the product that fail any of the in-process quality control tests.

b. Provide data to ensure that the condom manufacturing processes will not alter the molecular weight and molecular weight distribution of the material.

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c. Provide data on the quantities of residual solvent(s) and additives in condoms.

5. Material Toxicity

a. Provide toxicity data on all the monomers, additives, and solvents utilized in manufacturing of the material(s) of the condom if different from the standard thickness polyurethane condom.

b. Provide toxicity data on dusting agents and lubricants if different from the standard thickness polyurethane condom.

c. Provide biocompatibility data on the final product demonstrating that the condom does not produce acute and chronic toxicity, including mucosal irritation and sensitization.

6. Finished Product

a. Provide the device physical specifications including the length, width, thickness and mass.

b. Provide data from the following mechanical tests conducted on the final product:

1. elongation;

2. tear resistance and propagation;

3. air bust volume;

4. water leakage.

d. Provide data to demonstrate that the product's physical integrity is not compromised at body temperature, (i.e., force at break, tensile strength and elongation at 37°C).

7. Quality Assurance

a. Provide a detailed description of the test procedures, if different from the standard thickness polyurethane condom, used by the manufacturer to establish the quality of each condom lot or batch, including:

1. when testing is performed during the manufacturing processes;

2. a detailed description of any in process testing procedures including a description of the in process testing machine, the machine's specifications, and operator's manual and a description of the testing machine's calibration procedures;

3. data to demonstrate the sensitivity of the in process testing machine;

4. a description of the relationship between the in process testing machines' calibration procedures to the product release testing procedures; and

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

b. Provide the following information on the water leakage test if different from those of the standard thickness polyurethane condom:

1. a detailed description;

2. specifications;

3. operating procedures;

4. calibration procedures; and

5. validation to physical testing.

8. Packaging

Provide a description of the package material specification if different from that used for the standard thickness polyurethane condom.

9. Shelf-Life

Provide real-time and accelerated data to substantiate the shelf-life of the device, including an analysis for chemical degradation and mechanical properties over time under ideal conditions of temperature and humidity. The data should include a statistically valid sample size.

10. Permeability

Provide data from the in-vitro permeability studies to demonstrate the barrier properties of the condom with respect to sexually transmitted diseases (STDs) of appropriate size and that test the device under conditions that simulate actual use.

11. Clinical Data

Provide the results from a clinical study with a statistically valid sample size, to demonstrate the performance of the devices during use. This should include the breakage rate of the condoms during use, the slippage rate of the condoms during use and any adverse reactions experienced by study subjects. Also, provide clinical data to substantiate the claim "Extra Protection".

Please be advised that FDA will not permit any claims, explicit or implied, that your condom is "Allergy Free" or hypoallergenic.

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

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Recommendation:

The information identified above will need to be requested from the applicant.

J. Michael Kuchinski Date: 9/1/92

Colin M Pollard 9/2/92
Chief, Ob/Gyn Branch Date:

/ ✓ / Concur, with changes -- See AI letter

/ / Do Not Concur

Comments:

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

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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

JUNE 11, 1992

APEX MEDICAL TECHNOLOGIES, INC.
ATTN: ALICE A. DEPAUL
10064 MESA RIDGE COURT
SUITE 202
SAN DIEGO, CA 92121

510(k) Number: K922688
Received: 06-04-92
Product: "EXTRA PROTECTION" POLYURETHANE CONDOM

We have received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required.

The Safe Medical Devices Act of 1990 (SMDA), signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so within 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date, you may want to check with FDA to determine the status of your submission.

In addition, the SMDA requires all persons submitting a premarket notification submission to include either (1) a summary of the safety and effectiveness information in the premarket notification submission upon which an equivalence determination could be based (510(k) summary), OR (2) a statement that safety and effectiveness information will be made available to interested persons upon request (510(k) statement). Safety and effectiveness information refers to information in the premarket notification submission, including adverse safety and effectiveness information, that is relevant to an assessment of substantial equivalence. The information could be descriptive information about the new and predicate device(s), or performance or clinical testing information. We cannot issue a final decision on your 510(k) unless you comply with this requirement.

Although FDA acknowledges that the law provides the 510(k) submitter an alternative, FDA encourages manufacturers to provide a 510(k) statement to FDA and to make their safety and effectiveness information available to the public, excluding confidential manufacturing process information, in lieu of submitting a 510(k) summary to the agency until FDA promulgates a regulation on the content and format of 510(k) summaries. **Since the law**

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requires that FDA must make the 510(k) summary, or the source of information referred to in the 510(k) statement, publicly available within 30 days of making a substantial equivalence determination, we advise you that we may no longer honor any request for extended confidentiality under 21 CFR 807.95.

Additionally, the new legislation also requires any person who asserts that a device is substantially equivalent to a class III device to (1) certify that he or she has conducted a reasonable search of all information known, or otherwise available, about the generic type of device, AND (2) provide a summary description of the types of safety and effectiveness problems associated with the type of device and a citation to the literature, or other sources of information, upon which they have based the description (class III summary and certification). The description should be sufficiently comprehensive to demonstrate that an applicant is fully aware of the types of problems to which the device is susceptible. If you have not provided this class III summary and certification in your premarket notification, please provide it as soon as possible. We cannot complete the review of your submission until you do so.

Furthermore, the new legislation, section 522(a)(1), of the Act, states that if your device is a permanent implant the failure of which may cause death, you may be subject to required postmarket surveillance. If the premarket notification for your device was originally received on or after November 8, 1991, is subsequently found to be substantially equivalent to an Aneurysm Clip, Annuloplasty Ring, Artificial Embolization Device, Automatic Implanted Cardioverter Defibrillator System, Cardiovascular Intravascular Filter, Cardiovascular Permanent Pacemaker Electrode (Lead), Central Nervous System Fluid Shunt, Coronary Vascular Stent, Implantable Pacemaker Pulse Generator, Implanted Diaphragmatic/Phrenic Nerve Stimulator, Intracardiac Patch or Pledget, Intravascular Occluding Catheter, Replacement Heart Valve, Total Artificial Heart, Tracheal Prosthesis, Vascular Graft Prosthesis (less than 6 mm diameter), Vascular Graft Prosthesis (6 mm or greater diameter), Vena Cava Clip, or Ventricular Assist Device - Implant, you will be subject to the required postmarket surveillance and so notified of this determination in your substantially equivalent letter. (Some of the above listed types of devices may require a premarket approval application). This list is subject to change without notification. If you have any questions as to whether or not your device may be subject to postmarket surveillance or about this program, please contact the Postmarket Surveillance Studies Branch at (301) 227-8639.

Please note that the SMDA may have additional requirements affecting your device. You will be informed of these requirements as they become effective.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

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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
Chief, Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

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

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K922688

APEX MEDICAL TECHNOLOGIES, INC.

10064 Mesa Ridge Ct. • Suite #202
San Diego, CA 92121
(619) 535-0012 • FAX (619) 535-9715

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FDA/CDRH/ODE/DMC

May 29, 1992

Food and Drug Administration
Bureau of Medical Devices
Document Control Center (HFZ - 401)
1390 Piccard Drive
Rockville, MD 20850

Re: 510(k) Submission - "Extra Protection" Polyurethane Condom

Dear Sirs/Madam:

This letter is intended to serve as notification of our intention to manufacture and market an "extra protection" polyurethane condom. We request this "extra protection" polyurethane condom to be considered substantially equivalent to:

1) the polyurethane condom described in a previously accepted 510(k) application, 510(k) Premarket notification # K902936/A, accepted by FDA on March 6, 1991 referred to in the remaining portions of this submission as *standard thickness polyurethane condom*,

2) currently marketed "extra strength" latex rubber condoms, such as *Lifestyles™ Extra Strength Condoms*, and

3) currently marketed "standard" latex rubber condoms, such as the U.S. market leader, *Trojan-Enz™ with Special Receptacle End*.

The "extra protection" polyurethane condom is not intended to replace the *standard thickness polyurethane condom*. It is intended to provide condom users with an additional choice of polyurethane condom from which to choose. This "extra protection" condom is identical to the *standard thickness polyurethane condom* in all but three aspects. These three differences substantiate the "extra protection" claim. The differences are as follows:

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- The nominal single wall thickness specification of the new, "extra protection" polyurethane condom is .045 millimeters (approximately .00177 inches) compared to a nominal single wall thickness of .03 millimeters (.0012 inches) for the "standard" thickness polyurethane condom. This 50% increase in wall thickness provides extra strength which supports the claim of "extra protection." Even with this added thickness, this condom is still not as thick as a standard thickness latex condom due to the higher strength of the polyurethane compared to latex rubber.

- The AQL for water leakage in the test specified in ASTM Standard Specification for Rubber Contraceptives (Condoms) D 3492 will be an AQL=0.25 General Inspection Level I, (Mil/Ansi Spec 105), compared to AQL=0.4 General Inspection Level I, (Mil/Ansi Spec 105) for the *standard thickness polyurethane condom*, standard latex condoms and extra strength latex condoms. This change in AQL also supports the "extra protection" claim, by raising the quality standard to a new level.

- The labeling of the condom is also different from the labeling used for the *standard thickness polyurethane condom* to reflect the changes described above.

To support this application, we wish to include, by reference, all of the information contained in 510(k) notification # K902936/A, entitled "Polyurethane Condom". It is our intent not to deviate from any portion of this previously accepted 510(k) submission, except as noted above.

Details concerning the "extra protection" condom follows:

I. Draft Label Copy

Appendix A contains the draft label copy for this "extra protection" polyurethane condom. Support for the label copy is provided in the sections below.

II. Wall Thickness

The nominal wall thickness of the condom is 50% greater than the *standard thickness polyurethane condom*. The nominal thickness of this "extra protection" polyurethane condom is .045 millimeters. The specified single wall thickness range will be .045 millimeters +/- .008 millimeters, compared to .03 millimeters +/- .007 millimeters for the *standard thickness polyurethane condom*. The increased wall thickness, compared to the *standard thickness polyurethane condom* adds significant strength to this condom. The physical properties which result from this are discussed in the next paragraph.

III. Physical Properties and Label Claim Support

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The following tables show the physical strength properties of these condoms, relative to "standard" latex condoms and "extra strength" latex condoms. The data presented here clearly show that the "extra protection" polyurethane condom, is significantly stronger than "standard" latex condoms, the "extra strength" latex condoms, and the *standard thickness polyurethane condom*. Table I and Table II show strength of condoms as measured by the two industry accepted test methods, tensile testing as called for in the ASTM Specification, and air burst testing, as called for by international standards organizations, such as ISO and BSI respectively.

Table I - Tensile Strength Data

Condom		**Single Wall Thickness** (mm)	**Peak Load (Newtons)**	**Tensile Strength** (MPa)
"Extra Protection" Polyurethane Condom	Mean SD	.045 .004	110.9 9.9	61.0 4.3
Standard Thickness Polyurethane Condom	Mean SD	.035 .0015	86.1 11.8	60.8 9.0
"Standard Thickness" Latex Rubber Condoms (Trojan-Enz with Special Receptacle End)	Mean SD	.058 .0028	47.5 6.04	20.32 2.14
"Extra Strength" Latex Rubber Condom (Ansell Extra Strength)	Mean SD	.105 .0134	105.23 16.31	25.08 2.44

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Table II - Burst Strength Data

Condom		**Single Wall Thickness** (mm)	**Burst Pressure (kPa)**
"Extra Protection" Polyurethane Condom	Mean SD	.042 .0020	5.50 .293
Standard Thickness Polyurethane Condom	Mean SD	.028 .0010	3.88 .316
"Standard Thickness" Latex Rubber Condoms (Trojan-Enz with Special Receptacle End)	Mean SD	.061 .0016	1.34 .049
"Extra Strength" Latex Rubber Condom (Ansell Extra Strength)	Mean SD	.082 .0049	1.72 .143

Abbreviations used for both tables:

Mean = Mean of 5 Values

SD = Standard Deviation

mm = millimeters

N = Newtons

MPa = Megapascals

kPa = Kilopascals

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The physical properties support the proposed label claims, as follows:

The claim containing the wording *". . . twice as strong as latex . . ."* refers to the inherent strength of the materials of construction and is supported by the tensile strength data, which establishes the tensile strength of the polyurethane condoms to be at least double that of the tested latex rubber condoms. One of the latex condoms chosen for comparison was the market leader, Trojan-Enz™.

The claim of *"This technology has made it possible to make a stronger condom without sacrificing sensitivity"* is supported by the fact that the "extra protection" polyurethane condom is stronger than the "standard thickness" latex rubber condoms as shown by the higher peak load at break and the higher air burst pressure, while still being thinner than the "standard thickness" latex rubber condoms. To produce a stronger latex rubber condom, the wall thickness is typically increased to provide for extra strength, as is the case with the Ansell Extra Strength condoms. This extra wall thickness sacrifices sensitivity. The "extra protection" polyurethane condoms are thinner than either of the latex condoms, preserving sensitivity.

The *"extra protection"* claim is based upon 1) the demonstrated greater strength of the "extra protection" polyurethane condom relative to standard latex condoms, and 2) the more stringent AQL release criteria for the water leak test. The combination of these two factors supports the use of the "extra protection" wording. The fact that the "extra protection" polyurethane condom is stronger than the "extra strength" latex rubber condoms further supports this claim

IV. Place of Manufacture.

Apex Medical Technologies, Inc. and London International Group, plc. (parent company of Schmid Laboratories division of London International U.S. Holdings, Inc.) are combining efforts to achieve the earliest possible commercialization of the "extra protection" polyurethane condom (in addition to the standard polyurethane condom that has already been market cleared), consistent with the highest standards of quality assurance. Therefore, the initial locations for manufacturing will be on a site adjoining the research and development facilities of London International Group, plc. in Cambridge, England. This will allow for the close oversight and supervision of the production process by highly qualified individuals. Subsequent manufacturing is expected to be conducted in Anderson, South Carolina. The manufacturer's Device Establishment Numbers are as follows:

Schmid Laboratories, division of London International U.S. Holdings, Inc., Anderson, South Carolina, #1045600.

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Schmid Laboratories, division of London International U.S. Holdings, Inc., Sarasota, Florida # 2211046.

London International Group, Cambridge, England, # 8043984.

V. Availability of Safety and Effectiveness Information

A summary of this 510(k) is contained in Appendix B, which contains the required summary of safety and efficacy information.

VI. No changes to test methods, QA procedures, materials of construction, biocompatibility, etc.

(b) (4)

The manufacturing procedures to be used to produce this polyurethane "extra protection" condom will be very similar to that used for the standard thickness condom described in the previous 510(k). A process change that 1) uses a different dipping rate and 2) uses a higher percent solids dipping solution will be used to achieve the desired wall thickness. No other process changes are planned.

We consider our intent to market this "extra protection" polyurethane condom confidential commercial information, and request that this information be considered as such by the FDA. Additionally, some details contained in this letter are confidential in nature. We request the removal of the proprietary details of this submission from any potential disclosure under the Freedom of Information Act.

Should you require further information relating to this amendment, please contact me at (619) 535-0012.

Sincerely,

Alice A. DePaul

Alice A. DePaul
Vice President

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

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Appendix A

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

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EXTRA PROTECTION PACK LABEL

FRONT OF PACK

Technologically Advanced Condoms

Superior Non-Latex Condom

New Avanti™ Extra Protection Condoms are superior to latex condoms because they are made from a technologically advanced material which is twice as strong as latex. This technology has made it possible to make a stronger condom without sacrificing sensitivity.

Clear and Sensitive
Natural Feeling
No Odor
Allergy Free

Ultimate Strength -- Superior Sensitivity

Lubricated Condoms

(Net Contents Statement, as required by the Fair Packaging and Labeling Act.)

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

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BACK OF PACK

Avanti™ Extra Protection Condoms are made from a technologically advanced material which has allowed us to make them stronger than Extra Strength latex condoms, yet more sensitive than regular latex condoms.

PROPER USE OF CONDOMS

Avanti™ Condoms, when properly used, are highly effective against pregnancy -- although no contraceptive can guarantee 100% effectiveness. Any use of Avanti condoms for other than vaginal intercourse can increase the potential of damage to the condom. Avanti Condoms, when properly used, may help reduce the risk of catching or spreading Sexually Transmitted Diseases ("STD's") such as syphilis, gonorrhea, chlamydia infections, genital herpes and AIDS, however, it cannot eliminate the risk.

For maximum benefits, it is important to follow the instructions for use included with 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 STD's. Therefore, the condom should be applied each and every time before any such contact occurs.

Storage: Avoid prolonged storage of condoms at temperatures in excess of 100 degrees Fahrenheit -- storage for short period of time at this temperature will not be harmful to the product. Avoid any storage close to a hot radiator, hot air duct or similar object.

Distributed by: SCHMID LABORATORIES, DIVISION OF LONDON INTERNATIONAL U. S. HOLDINGS, INC., SARASOTA, FLORIDA 34230-4703.

(Labeling of date of manufacture.)

(Country of origin statement in compliance with Customs and Federal Trade Commission Regulations.)

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

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Appendix B

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

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510(k) Summary
Statement of Safety and Effectiveness

I.	**Submitter's Name:**	Apex Medical Technologies, Inc. 10064 Mesa Ridge Court, Suite 202 San Diego, CA 92121
II.	**Submitter's Phone Number:**	(619) 535-0012
III.	**Contact Person:**	Alice A. DePaul, Vice President
IV.	**Date of Preparation:**	May 29, 1992
V.	**Name of Device:**	"Extra Protection Polyurethane Condom"
VI.	**Trade or Proprietary Name:**	"Extra Protection Condom"
VII.	**Common or Usual Name:**	Condom
VIII.	**Classification Name:**	Condom
IX.	**Predicate or legally marketed device or devices to which substantial equivalence is claimed:**	Currently marketed latex condoms and the polyurethane condom described in 510(k) Premarket notification # K902936/A, accepted by FDA on March 6, 1991.

X. General Description of the diseases or conditions the device will diagnose, treat,prevent, cure or mitigate, including a description of the patient population for which the device in intended:

This condom is intended to aid in the prevention of pregnancy, and is intended to help prevent the transmission of sexually transmitted diseases. The patient population for which this product is intended is as follows: people who engage in vaginal intercourse who wish to reduce the likelihood of becoming pregnant and/or contracting sexually transmitted disease(es). This condom is not intended for people who expect absolute protection. People requiring absolute protection from pregnancy and/or sexually transmitted diseases should consult their physicians for alternatives.

XI. Description of Device:

The "Extra-Protection Polyurethane Condom" is a combination contraceptive and disease prevention device which functions by acting as a barrier to the transfer of semen and/or infective microorganisms known to cause sexually transmitted diseases. This barrier protection is intended to be effective for vaginal intercourse only. The basis for function of this device is based upon the fact that these condoms are essentially pore-free and will not allow for the passage of spermatozoa or disease organisms between sexual partners during vaginal intercourse.

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

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The main cylindrical portion of the "Extra-Protection Polyurethane Condom" is produced from a material called polyurethane. The open end of the condom has a ring made from a proprietary synthetic rubber material which is softer than the polyurethane to provide for added comfort to the user.

XII. Description of Non-Clinical Tests and Their Results

The results of physical properties testing support the substantial equivalency claims. The results of the physical properties tests show the polyurethane condoms to have higher tensile strengths, and air burst pressures than currently marketed latex condoms. Average air burst pressure for this polyurethane condom was shown to be 5.50 kilopascals, compared to 1.34 kilopascals for standard thickness latex condoms and 1.72 kilopascals for extra strength latex condoms. The average tensile strength for this polyurethane condom was shown to be 61.0 megapascals, compared to 20.32 megapascals for standard thickness latex condoms and 25.08 megapascals for extra strength latex condoms.

The release criteria for this condom is based upon the water leakage test described in ASTM Standard Specification for Rubber Contraceptives (Condoms) D 3492 and will be set to a level of AQL=0.25 General Inspection Level I, (Mil/Ansi Spec 105), compared to AQL=0.4 General Inspection Level I, (Mil/Ansi Spec 105) for standard latex condoms and extra strength latex condoms.

XIII. Conclusions drawn from nonclinical and clinical tests that demonstrate the device is "safe, effective and performs as well or better than the currently legally marketed device".

Based upon superior physical properties, and based upon a more stringent product release criteria, this condom is expected to be substantially equivalent to and superior to currently marketed latex condoms.

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