

**TROJAN® Polyurethane Condom
with Spermicidal Lubricant
510(k) #K955672 — Additional Information**

AUG 29 1995

Page 827

October 30, 1995

510(k) SUMMARY

K955672

Submitted by: Carter-Wallace, Inc.
Carter Products Division
P.O. Box 1001
Cranbury, NJ 08512
(609) 655-6000

Contact Person: Stephen C. Kolakowsky

Date Prepared: October 30, 1995

Name of Device: TROJAN® Polyurethane Condom
with Spermicidal Lubricant

Classification Name: Condom with Spermicidal Lubricant

Predicate Device: TROJAN® Latex Condoms

Description of the Device: A condom is a sheath which completely covers the penis with a closely fitting membrane. The membrane in the case of the subject medical device is made of a polyurethane material. The polyurethane utilized for the TROJAN® Polyurethane Condom is an aliphatic polyurethane. Unlike an aromatic polyurethane, the aliphatic polyurethane utilized for the TROJAN® Condom does not have the inherent danger of forming methylene dianiline (MDA), a known carcinogen, which can be leached from some aromatic polyurethane materials. The condom provides a physical barrier between the penis and vagina thus, when properly used, reducing the risk of exchange of semen, other body fluids, or microorganisms during sexual intercourse. The subject condom is approximately 59 mm in width and approximately 180 mm in length, with a reservoir tip at the closed end and an integral ring (rim) at the open end. The subject condom is one of two versions intended to be marketed — this version with spermicidal lubricant (nonoxynol-9, 8%) and the other with a silicone lubricant. In consumer use studies with heterosexual couples, the subject device was found to have equivalent performance to that of the predicate device with regard to the parameters of breakage and slippage.

Intended Use of the Device: The subject polyurethane condom has the same intended use as the predicate latex condoms. The condom is used for contraceptive and for prophylactic purposes (helping to prevent transmission of venereal disease). If used properly, condoms will help to reduce the risk of transmission of HIV infection (AIDS) and many other sexually transmitted diseases, including chlamydia, genital herpes, genital warts, gonorrhea, hepatitis B, and syphilis. No contraceptive can guarantee 100% effectiveness. Any use of the condom for other than vaginal intercourse can increase the potential of damage to the condom. For

TROJAN® Polyurethane Condom
with Spermicidal Lubricant
510(k) #K955672 — Additional Information

Page 828

October 30, 1995

510(k) SUMMARY (cont'd)

maximum benefits, it is important to follow the instructions for use that accompany the product. 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 sexually transmitted diseases (STDs); therefore, a new condom should be applied each and every time before any such contact occurs. The condom with spermicidal lubricant combines the use of a condom with a spermicidal lubricant. The spermicide, nonoxynol-9, reduces the number of active sperm, thereby decreasing the risk of pregnancy if erection is lost before withdrawal and some semen spills outside the condom. However, the extent of decreased risk has not been established. A condom with spermicidal lubricant should not be used as a substitute for the combined use of a vaginal spermicide and a condom.

Technological Characteristics: The subject device differs from the predicate device in its material composition, *i.e.*, the subject device is composed of polyurethane and the predicate device is composed of natural rubber latex. The subject device, therefore, does not have the inherent potential for latex protein sensitization or latex protein allergic reaction as does a latex condom. Also due to the inherent nature of the polyurethane material as compared to natural rubber latex, the subject condom is stronger (has a higher tensile strength and break force), has a lower ultimate elongation, and is more resistant to deterioration by oil and oil-based materials, UV light, and oxidation. The barrier properties of the subject polyurethane condom were compared to those of a latex condom in a viral permeability study. The results of this study demonstrate that the subject polyurethane condom has equivalent barrier properties to that of a typical latex condom for preventing the transmission of small viral particles across the condom membrane. Toxicological studies performed provided no indication for toxicological concern. In consumer use studies with heterosexual couples, the subject polyurethane condom was found to have equivalent performance to that of a typical latex condom with regard to the parameters of breakage and slippage. Thus, although the subject polyurethane condom has different technological characteristics, *i.e.*, a different material composition, than that of the predicate latex condoms, the difference does not raise different questions of safety and efficacy. The subject polyurethane condom is, therefore, substantially equivalent in terms of safety and effectiveness, in helping to prevent pregnancy and in helping to reduce the risk of transmission of HIV infection (AIDS) and other sexually transmitted diseases (STDs), to the predicate latex condoms currently marketed.


George H. Ohye
Corporate Vice President
Compliance and Regulatory