

VII. INDICATIONS FOR USE STATEMENT

510(k) Number: Not available yet *K993781*

Device Name: *Simplex brand Male Rubber Latex Condom (Silicon Lubricated)*

Indications For Use: The Simplex brand condom is a male contraceptive device, fabricated of natural latex, which is designed to completely cover the penis during sexual intercourse. This condom is intended to be used for contraception and for prophylactics purposes. If used properly, this condom will help 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. In addition, this condom will help reduce the risk of pregnancy without the serious side effects sometimes associated with other methods. However, no contraceptive can guarantee 100 % effectiveness. Failure to use as directed, may further result in loss of protection. Furthermore, sexually transmitted diseases can be transmitted through lesions and various body fluids, during intimate contact. Therefore, the condom should be applied before any such contact.

Concurrence of CDREI, Office of Device Evaluation (ODE)

Prescription Use OR Over-The-Counter Use

David G. Beggs
 (Division Sign-off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices