

**II. 510(k) SUMMARY**

Submitted By: UNIDUS Corporation  
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Songpa-Ku  
Seoul, Republic of Korea

Contact Persons: Eli J. Carter  
Consultant to UNIDUS Corporation  
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Seokyeong Building 51,  
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Seoul, Korea

Date Prepared: September 18, 2002

Proprietary Name: UNIDUS, (and other private labels)

Common Name: Male Latex Condom

Classification Name: Male Latex Condom

Predicate Device: LS Rubber Latex Condom; K020633

Description of Device: This condom is made of a natural latex sheath, which completely covers the erect penis with a closely fitted membrane. This condom is straight-walled with a reservoir tip; nominal length 180-mm, nominal width 52-mm, nominal thickness 0.06mm and is colored. It is lubricated with silicone containing flavoring, and cornstarch is used as a dressing material. This condom is designed to conform to established national and international voluntary standards including ASTM D3492 and ISO 4074.

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

Technological Characteristics: This condom has the same technological characteristics as the predicate condom identified above. The design is in conformance with ASTM Latex Condom Standard D3492 and that the condom is made of natural rubber latex.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DEC 13 2002

Unidus Cororation  
% Mr. Eli J. Carter  
Consultant  
1219 Little Creek Road  
DURHAM NC 27713

Re: K023175

Trade Name/Device: Male Natural Rubber Latex Condom (colored and flavored)  
Regulation Number: 21 CFR 884.5300  
Regulation Name: Condom  
Regulatory Class: II  
Product Code: 85 HIS  
Dated: September 18, 2002  
Received: September 23, 2002

Dear Mr. Carter:

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 (for the indications for use stated in the enclosure) to legally marketed predicate 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.

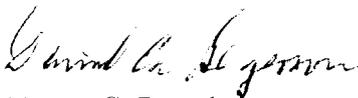
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

Please be advised that, as of March 25, 1998, labeling for latex condoms (21 CFR §884.5300 and §884.5310) must comply with Use Labeling for Latex Condoms: Expiration Dating, 21 CFR 801.435. Therefore, an expiration date, supported by test data developed under the conditions specified in §801.435(d), must be displayed prominently and legibly on condom labeling. For condoms with spermicidal lubricant, the effective shelf life of the spermicide must be compared with the shelf life of the condom and labeled with the earlier of the two expiration dates. Although supporting data is not to be provided in your 510(k) submission, §801.435(j) requires that you maintain this data and that it be available for inspection by FDA. Furthermore, §801.435(e) requires that if your real-time test data fails to confirm the shelf life estimated by the methods in §801.435(d), then you must relabel all product to reflect the actual shelf life. Condoms are not to be labeled with an expiration date that gives a shelf life more than five years.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR §807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



*NCB*  
Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health  
cc: HFZ-401

**VII. INDICATIONS FOR USE STATEMENT**

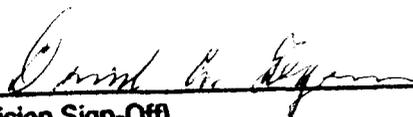
510(k) Number            Not Known

Device Name              Male Natural Rubber Latex Condom (colored and flavored)

Indications for Use:      The UNIDUS condom is used for contraceptive and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted diseases)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEED  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_ OR Over-the-Counter Use  \_\_\_\_\_  
(Per 21 CFR 801.109)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number 2023125