DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 7 2001

Mr. Peter Park
General Manager
DONGKUK TECHCO Rubber
Industries SDN. BHD.
7th Floor, Mayban Trust Bldg.
3 Penang Street
Penang 10200
MALAYSIA

Re: K990669
Trade/Device Name: Natural Ordinary, Natural Ribbed, Natural Dotted and Natural Contoured (Multiple-Brand Male Latex Condom, Lubricated with Nonoxynol-9)
Regulation Number: 21 CFR §884.5310
Regulation Name: Condom with spermicidal lubricant
Regulatory Class: II
Product Code: 85 LTZ
Dated: February 22, 1999
Received: March 2, 1999

Dear Mr. Park:

This letter corrects our substantially equivalent letter of May 17, 1999 regarding the Natural Ordinary, Natural Ribbed, Natural Dotted and Natural Contoured (Multiple-Brand Male Latex Condom, Lubricated with Nonoxynol-9) in which the product code was listed incorrectly.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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 (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 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 and additionally Part 809.10 for in vitro diagnostic devices), 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. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

VII. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K990669

Device Name: Natural Ordinary, Natural Ribbed, Natural Dotted and Natural Contoured (Multiple-brand Male Latex Condom, Lubricated with Nonoxynol-9)

Indication for Use:

THESE DIFFERENT TYPES (NATURAL ORDINARY, NATURAL RIBBED, NATURA DOTTED, AND NATURAL CONTOURED) OF NATURAL LATEX RUBBER CONDOM (WITH NONOXYNOL-9) ARE USED FOR CONTRACEPTION AND FC PROPHYLACTIC PURPOSES (TO PREVENT PREGNANCY AND THE TRANSMISSIC OF SEXUALLY TRANSMITTED DISEASES (STD'S).

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use ✓

(Per 21 CFR §801.109)

(Div... ...tive, Abdominal, ENT, and ... ...ices

510(k) Number K990669

2

... (Multiple Brand) Abbreviated 510(k) Notification to FDA