



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room - WO66-G609  
Silver Spring, MD 20993-0002

Thai Nippon Rubber Industry  
c/o Mr. Eli Carter  
Consultant  
Eli Carter and Associates  
PO Box 12139  
DURHAM NC 27709

OCT 16 2009

Re: K081265

Trade/Device Name: Thai Nippon Male Latex Condom 56mm (nominal width), flared,  
Colorless, silicone lubricated

Regulation Number: 21 CFR §884.5300

Regulation Name: Condom

Regulatory Class: II

Product Code: HIS

Dated: September 28, 2009

Received: October 5, 2009

Dear Mr. Carter:

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) that do not require approval of a premarket approval application (PMA). 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); medical device reporting (reporting of medical

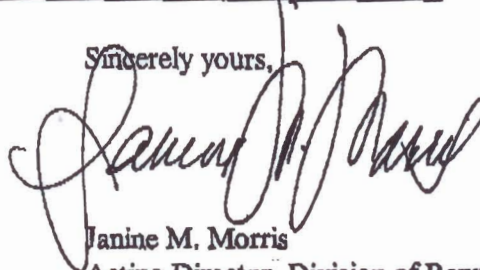
Page 2 -

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Janine M. Morris  
Acting Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

Information for a Male Latex Condom 510(k) Submission

II. INDICATIONS FOR USE STATEMENT

510(k) Number: K081265

Device Name: Thai Nippon Male Latex Condom  
56mm (nominal width), flared, colorless, silicone  
lubricated

Indications for Use: The Thai Nippon Male Latex Condom is used for  
contraception 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 NEEDED)  
Concurrence of CDRH, Office of Device Evaluation (ODE)

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

[Signature]  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K081265