DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 0 9 2004

Thai Nippon Rubber Industry, Ltd.
c/o Eli Carter, Ph.D.
Consultant to Thai Nippon.
Family Health International
2224 E NC Highway 54
DURHAM NC 27713

Re: K011253/A1 and A2
Device Name: Male Latex Condom, Colored with Flavored Lubricant
Dated: September 5, and 29, 2003
Received: September 16, and October 1, 2003

Dear Dr. Carter:

We have reviewed the information dated September 5 and 29, 2003, regarding a design change for the Colored Male Latex Condom with Flavored Lubricant with the addition of alternative colors (green and brown) and flavored lubricant (mint-lime and chocolate) system for the 510(k) notification K011253 previously submitted for the device referenced above. Based solely on the information that you have provided, it does not appear that you have significantly changed or modified the design, components, method of manufacture, or intended use of the device referenced above (see 21 CFR 807.81(a)(3)). It is, however, your responsibility to determine if the change or modification to the device or its labeling could significantly affect the device's safety or effectiveness and thus require submission of a new 510(k). As with your initial 510(k), reference number K011253, it is expected that this new condom will also conform with ASTM D 3492:97 and ISO 10993-1:1997 according to the nature of body contact and duration of contact. The information you have supplied will be added to the file.

Sincerely yours,

Nancy C Brogdon

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