DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Thai Nippon Rubber Industry Co., Ltd.
c/o Mr. Eli J. Carter
Technical Consultant
1219 Little Creek Road
DURHAM NC 27713

JUN 18 2004

Re: K994095/A3
Device Name: Thai Nippon Male Latex Condoms (Flared Smooth, Contour Smooth and Contour Textured(ribbed and dotted)) with Silicone Lubricant
Dated: April 13, 2004
Received: April 20, 2004

Dear Mr. Carter:

We have reviewed the information dated April 13, 2004, regarding design changes to the One Touch™ Latex Condom that includes the addition of a Flared Smooth, Contour Smooth and Contour Textured(ribbed and dotted) for the 510(k) notification K994095 previously submitted for the device referenced above. Based solely on the change or modification that you have described, 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)). Additionally, we did not review any data submitted with this add to file. 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). Please refer to our guidance document entitled, "Deciding When to Submit a 510(k) for a Change to an Existing Device" at www.fda.gov/cdrh/ode/510kmod.html. As with your initial 510(k), reference number K994095, 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,

David A. Segroves

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