9. 510 (k) Summary of Information Respecting Safety and Effectiveness

A. Legally Marketed Device.

Qualis Claims substantial equivalence to K-Y Brand Warming Liquid Personal Lubricant (K021492), currently in commercial distribution by Personal Products Company Division of McNeil-PPC inc..

B. Device Description.

Personal Warming Lubricant is a non-sterile, clear, non-staining, non-greasy, high viscosity liquid gel used as a personal lubricant. This product is highly lubricous and may be used with or without a latex condom during intimate sexual activity.

C. Intended Use.

Personal Warming Lubricant is designed to enhance the ease and comfort of intimate activity and is compatible with latex condoms.

D. Comparison with Predicate Device.

A summary comparison of the features of Personal Warming Lubricant and the Predicate Device K-Y Brand Warming Liquid Personal Lubricant is provided in Table 1.

E. Performance Data

Non-Clinical Studies.

1. Stability.

Personal Warming Lubricant has successfully passed 90 day accelerated stability.

2. Preservative Effectiveness.

Personal Warming Lubricant successfully passed the requirements of the Qualis, Inc., anti-microbial preservative challenge. See Attachment D for the Preservative Effectiveness Study Report

3. Comparison with Predicate Device.

Personal Warming Lubricant was compared to K-Y Brand Warming Liquid Personal Lubricant on the basis of perceptual qualities, physical and chemical properties, ingredients list review, label claims, and packaging. The result of this review was an acceptable comparison. See Attachment B for the ACTS comparison Report.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 0 2004

Mr. Mike Peterson
Quality Assurance Manager
Qualis, Inc.
4600 Park Avenue
DES MOINES IA 50321

Re: K040085
Trade/Device Name: Personal Warming Lubricant
Regulation Number: 21 CFR §880.6375
Regulation Name: Patient Lubricant
Product Code: 80 MMS
Regulation Number: 21 CFR §884.5300
Regulation Name: Condom
Product Code: 85 HIS
Regulatory Class: II
Dated: January 15, 2004
Received: January 23, 2004

Dear Mr. Peterson:

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); 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 begin 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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" (21CFR Part 807.97) you may obtain. 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,

Nancy C. Brogdon

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

Enclosure

Indications for Use

510(k) Number (if known): K040085

Device Name: Personal Warming Lubricant

Indications For Use: Personal Warming Lubricant is designed to enhance the ease and comfort of intimate activity and is compatible with latex condoms

Prescription Use _____ ~~AND~~/OR Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040085