



Food and Drug Administration
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June 14, 2016

Guy & O'Neill, Inc.
% John Ziobro
Principal Consultant
SpectraMedEx, LLC
3215 Golf Road, #149
Delafield, WI 53018

Re: K160717
Trade/Device Name: ally® Warming Liquid Personal Lubricant
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: Class II
Product Code: NUC
Dated: May 24, 2016
Received: May 26, 2016

Dear John Ziobro,

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 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 contact the Division of Industry and Consumer Education 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>. 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 Industry and Consumer Education 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,


Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K160717

Device Name
ally® Warming Liquid Personal Lubricant

Indications for Use (Describe)

ally® Warming Liquid is a personal lubricant, for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Traditional 510(k) Summary

1. Date Prepared: June 11, 2016
2. Applicant Name & Address: Guy & O'Neill, Inc.
200 Industrial Drive
Fredonia, WI 53021, USA
3. Submission Correspondent: John F. Ziobro
Principal Consultant
SpectraMedEx, LLC
3215 Golf Road, #149
Delafield, WI 53018
262.719.8922
4. Trade Name: ally® Warming Liquid Personal Lubricant
5. Common Name: Personal Lubricant
6. Regulation: 21 CFR 884.5300
7. Class: II
8. Classification Name: Condom
9. Product Code: NUC
10. Predicate Device: K-Y Brand Warming Liquid Personal Lubricant (K021492)
11. Indication for Use:

ally® Warming Liquid is a personal lubricant, for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.

12. Device Description:

The device is 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 natural rubber latex or polyisoprene condom during intimate sexual activity. This product is not a contraceptive or spermicide. The product is packaged in 2 to 8 ounce plastic bottles with tamper-proof seals.

INGREDIANTS: Glycerin, propanediol

13. Technological Characteristics:

This product is a glycerin-based personal lubricant, and its ingredients and physical parameters are comparable to the predicate device.

14. Summary of Performance Data:

Biocompatibility, microbiology, condom compatibility and shipping testing were conducted on the device by outside laboratories, in compliance with the following recognized consensus standards:

- ASTM D7661-10, *Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms* for compliance with latex and polyisoprene condoms.
- ISO 10993-5 *Biological Evaluation of Medical Devices-Part 5: Tests for in vitro cytotoxicity*
- ISO 10993-10 *Biological Evaluation of Medical Devices-Part 10: Tests for irritation and skin sensitization*
- ISO 10993-11 *Biological Evaluation of Medical Devices-Part 11: Tests for systemic toxicity*
- United States Pharmacopeia, National Formulary General Chapter <88>: *Biological Reactivity Tests, In Vivo*
- USP <51> Antimicrobial Effectiveness Testing
- USP <61> Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests
- USP <62> Microbiological Examination of Nonsterile Products: Tests for Specified Microorganisms
- ISTA 3A: *Packaged-Products for Parcel Delivery System Shipment 70 Kg (150 lb) or Less*

SHELF LIFE TESTING:

Both accelerated and real time stability studies were performed on the ally® Warming Liquid per ICH Q1A(R2) Guidelines. The device will be launched with a 10-month shelf life based on accelerated aging and then re-labeled with 2- and 3-year shelf life once the results of the real-time testing are completed.

15. Conclusions

The proposed Ally® Warming Liquid Personal Lubricant and the predicate device (K021492) have the same intended use and comparable technological characteristics. The differences in specific ingredients do not raise any different types of questions. Performance data demonstrated that the subject device is substantially equivalent to the predicate device in terms of safety and effectiveness.