DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 6, 2016

Mano and Mano Proprietary Limited
% Gary Mocnik
Regulatory Consultant
ClinReg Consulting Services, Inc.
733 Bolsana Drive
Laguna Beach, CA 92651

Re: K161585
Trade/Device Name: Mano and Mano Personal Lubricant (also branded as Nooky, Hello Sailor, or Lulu)
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: Class II
Product Code: NUC
Dated: June 6, 2016
Received: June 8, 2016

Dear Gary Mocnik:

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,

Joyce M. Whang -S

for 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161585

Device Name
Mano and Mano Personal Lubricant (additionally branded as Nooky, Hello Sailor, or Lulu)

Indications for Use *(Describe)*
Mano and Mano Personal Lubricant is a water-based personal lubricant, for penile and/or vaginal application, intended to lubricate and moisturize, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is not compatible with natural rubber latex, polyurethane, and polyisoprene 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.

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510(k) Summary
(K161585)

Applicant: Mano and Mano Proprietary Limited
286 Chesterville Rd
Moorabbin, Victoria 3189
Australia

Contact: Gary Mocnik
ClinReg Consulting Services, Inc.
733 Bolsana Drive
Laguna Beach, CA 92651
Phone: 949-433-0413
E-mail: gmocnik@cox.net

Date Prepared: August 16, 2016

Proprietary Name: Mano and Mano Personal Lubricant (also branded as Nooky, Hello Sailor, or Lulu)

Common Name: Personal Lubricant

Regulation Number: 21 CFR 884.5300

Regulatory Class: Class II

Product Code: NUC

Predicate Device: Poise Personal Lubricant (K120650)

Device Description:

Mano and Mano Personal Lubricant (additionally branded as Nooky, Hello Sailor, or Lulu) is a clear, colorless, water-based personal lubricant composed of purified water, propylene glycol, hydroxethyl cellulose, sodium pyrrolidone carboxylic acid, potassium sorbate and citric acid.

This product has an initial shelf-life of 10 months. The shelf-life will be extended pending completion of further study.

Indications for Use:

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

Substantial Equivalence Discussion

The subject and predicate devices have the same indications. They both are clear, colorless, water-based personal lubricants. Although there are differences in pH, osmolality, viscosity and formulation of these devices, the differences do not represent a new technology as they do not raise different questions of safety and effectiveness.

Performance Data

Bench testing demonstrated that the subject device met the physical specifications (appearance, pH, viscosity and, osmolality) and the following microbiology specifications:

Criteria	Specifications	Methods
Total Aerobic Microbial Count	≤100 cfu/g	USP <61>
Total Yeast and Mold Count	≤10 cfu/g	USP <61>
Absence of Pathogenic Organisms	Absence of pseudomonas aeruginosa, staphylococcus aureus, and candida albicans	USP <62>
Antimicrobial Effectiveness	At least 2.0 log reduction from the initial count at 14 days; no increase from the 14 days count at 28 days; no increase from the initial calculated count at 14 and 28 days	USP<51>

Shelf-life (stability) testing conducted by a third-party laboratory demonstrated that the subject device maintained all physical and microbiology specifications at the end of shelf-life period.

The subject device has passed the following biocompatibility testing in accordance with relevant ISO standards:

- Cytotoxicity (ISO 10993-5:2009)
- Sensitization (ISO 10993-10:2010)
- Irritation (ISO 10993-10:2010)
- Acute Systemic Toxicity (ISO 10993-11:2006)

Conclusion:

The subject and predicate devices have the same indications and fundamental technological characteristics. The differences in technological characteristics do not raise different types of questions and can be assessed by bench and biocompatibility testing. Performance data demonstrates that the subject device is substantially equivalent to the predicate device in terms of safety and effectiveness.