April 19, 2018

ICM Pharma Pte Ltd
Moturi Srinivasa Rao
Regulatory Affairs Manager
26 Kallang Place #05-17
Singapore, 339157 Sg

Re: K172306
Trade/Device Name: SuperSlyde Personal Lubricant
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: March 15, 2018
Received: March 19, 2018

Dear Moturi Srinivasa Rao:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172306

Device Name
SuperSlyde Personal Lubricant

Indications for Use *(Describe)*
SuperSlyde lubricant 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 condoms. This product is not compatible with 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.

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510(k) Summary

K172306

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Date Prepared:	08/03/2018
Proposed Trade Name:	SuperSlyde Personal Lubricant
Common Name:	Personal Lubricant
Classification Name:	Condom 21 CFR884.5300 Class II NUC (lubricant, personal)
Predicate Device	Wet Platinum Premium Lubricant 510(k) No: K130012 The predicate device has not been subject to a design related recall.
Device Description:	SuperSlyde is an anhydrous, non-sterile, clear, silicone-soluble liquid for use as a personal lubricant. It is made of dimethicone and dimethiconol. The specifications for SuperSlyde include appearance, color, odor, viscosity, total aerobic microbial count per USP <61>, total yeast and mold count per USP <61> and absence of pathogenic organisms per USP <62>. Osmolality, pH and antimicrobial effectiveness test parameters are not applicable because the subject lubricant is non-aqueous based formulation. The product is packaged in a polyethylene terephthalate (PET) bottle with a screw-on, press-top polypropylene (PP) in volumes of 100ml, 250ml and 400ml.
Indications for Use:	SuperSlyde lubricant 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 condoms. This product is not compatible with polyurethane and polyisoprene condoms.
Technological Characteristics:	SuperSlyde has similar ingredients to the predicate device. However, SuperSlyde and the predicate device have different technological characteristics, including their formulation and specifications. The differences in technological characteristics do not raise different questions of safety or effectiveness.

Summary of Performance Testing:

Biocompatibility:	SuperSlyde Personal Lubricant has undergone biocompatibility testing including cytotoxicity, sensitization, vaginal irritation and acute systemic toxicity testing per ISO 10993-5:2009, ISO 10993-10:2010, ISO 10993-10:2010 and ISO 10993-11:2006, respectively. The testing found that SuperSlyde Personal Lubricant is biocompatible.
Condom Compatibility	The compatibility of the subject device with natural rubber latex, polyisoprene, and polyurethane condoms was evaluated in accordance with ASTM D7661-10 Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms. The results of this test demonstrated that the subject device is compatible with natural rubber latex condoms. This product is not compatible with polyisoprene and polyurethane condoms.
Shelf Life Testing:	The results of shelf life testing demonstrate that the subject device meets its specifications over the duration of its proposed shelf life.
Conclusion:	The performance data demonstrate that the SuperSlyde Lubricant is substantially equivalent to its proposed predicate device.