Section 5. 510(K) Summary

Summary of Safety and Effectiveness Information

Submitter's Name:	Kimberly-Clark Corporation
Submitter's Address:	2100 Winchester Road Neenah, WI 54956 Mailing address for regulatory correspondence: 1400 Holcomb Bridge Road Roswell, GA 30076-2199 Contact Person: Swarna Mukund Ph. D.
Submitter's Phone No:	770-587-8083
Submitter's Fax No.	920-225-3632
Date of Preparation:	February 29, 2012
Trade Name:	Poise® Personal Lubricant
Device Common Name:	Personal Lubricant
Classification Name:	Condom
Classification Product Code:	NUC (Lubricant, Vaginal, Patient, Latex Compatible)
Regulation Number:	21CFR884.5300
Regulatory Class:	Class II
Legally marketed device to which equivalency is claimed:	Durex® Play™ Lubricant (K032124) (Marketed as Durex® Play™ More)
Intended Use:	Poise Personal Lubricant is a personal lubricant, for penile and/or vaginal application, intended to moisturize and lubricate, 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 condoms but is compatible with polyisoprene and polyurethane condoms.

Description of the device:

Poise Personal Lubricant is a water soluble, clear, colorless, viscous liquid composed of purified water, hydroxyethyl cellulose (Natrosol 250), propylene glycol, benzoic acid and sodium hydroxide. Poise Personal Lubricant is presented as a non-sterile product. It is neither a contraceptive nor a spermicide and is sold over-the-counter. The product is packaged in a seventy-four ml plastic, cylindrical pump bottle placed inside a display carton. The outside of the display carton contains a tamper evident seal. Poise Personal Lubricant is a non-greasy and fragrance-free formulation which contains only United States Pharmacopeia (USP) or National Formulary (NF) ingredients.

Summary of technological characteristics compared to the predicate device:

Poise Personal Lubricant has been shown to be substantially equivalent to the predicate device Durex Play More in terms of technological characteristics such as being water-based and non-sterile, color/appearance/odor, pH, viscosity, specific gravity, osmolality and long-lasting lubricity measured as coefficient of friction. Poise Personal Lubricant and Durex Play More contain identical formulation components. Stability studies conducted in accordance with ICH Q1a and Consumer Health Products Association (CHPA) stability guidelines confirm a shelf life of two years for the Poise Personal Lubricant product; the same as that for the predicate device, Durex Play More.

Durex Play More is labeled as condom compatible whereas the label for Poise Personal Lubricant says that the product is not compatible with natural rubber latex condoms but is compatible with polyisoprene and polyurethane condoms in condom compatibility testing conducted according to the standards defined by ASTM-D7661-10. No new questions of safety or effectiveness are presented.

Based on the comparisons above, nonclinical performance data, biocompatibility review and testing and safety data, we conclude that Poise Personal Lubricant and Durex Play More are substantially equivalent with regards to the general intended use, safety and efficacy.

Brief description of preclinical toxicology (biocompatibility) tests:

Table 5-1 provides the biocompatibility tests conducted and the results obtained for Poise Personal Lubricant.

Table 5-1: Biocompatibility Test Results of Poise Personal Lubricant

Endpoint of Toxicological Concern	Study Type	Reference	Result
Cytotoxicity	*In Vitro* Cytotoxicity	10993-05	*Non-cytotoxic ≤ 3.13%
Sensitization	*In Vivo* - Guinea Pig Maximization Assay	10993-10	Non-sensitizing
Vaginal Irritation	Rabbit Vaginal Irritation	10993-10	Non-irritating
Subacute Toxicity	Two week, Rabbit Vaginal Exposure	10993-11	Non-systemically toxic
Genotoxicity	*In vitro* Bacterial Reverse Mutation	10993-03, OECD 471	Non-genotoxic
	In vitro Chromosome Aberration	10993-03, OECD 473	Non-genotoxic
	In Vivo Mouse Micronucleus	10993-03, OECD 474	Non-genotoxic
Ocular Irritation	*In Vitro*, 3D Cell Culture (EpiOcular)	MatTek EpiOcular MTT Viability Assay	Non-irritating

*This formulation contains Propylene Glycol which in vitro has a moderate cytotoxic potential. Cytotoxicity is not demonstrated in vivo for propylene glycol or for Poise Personal Lubricant.

Oral Toxicity Assessment: The components of the Poise Personal Lubricant formulation have been individually assessed for oral toxicity. These components are Generally Recognized as safe (GRAS) with use levels significantly less than accepted ingestible amounts. Hence, the lubricant product is assessed as Non-Toxic with regards to oral toxicity.

Preclinical Microbiological Testing:

Microbial Limits Test was conducted on three process validation lots as per USP <61> and <62>. The product release specification for this test is ≤ 100 cfu (colony forming unit)/ml and no objectionable organisms to meet lot acceptance criteria. It was found that all three process validation lots met the specification for microbial limits testing by meeting the USP criteria.

Safety and Effectiveness Assessment:

The subject 510(k) device has undergone extensive biocompatibility, microbiological, stability, and nonclinical laboratory performance testing as described above and in subsequent sections. The results of these studies support the conclusion that the subject 510(k) device is equivalent and as safe and effective as the predicate device, Durex Play More.

Conclusions:

Based on the results of biocompatibility testing and nonclinical performance testing, Poise Personal Lubricant is safe for its intended use and is substantially equivalent to the predicate device, Durex Play More, in terms of general intended use, safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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JUL 11 2012

Re: K120650
Trade/Device Name: Kimberly-Clark* Poise® Personal Lubricant
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: July 2, 2012
Received: July 3, 2012

Dear Dr. Mukund:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Kimberly-Clark Corporation

INDICATIONS FOR USE

Applicant:	**Kimberly-Clark Corporation**
510(k) Number:	K120650
Device Name:	Kimberly-Clark* Poise® Personal Lubricant
Indications for use:	Poise Personal Lubricant is a personal lubricant, for penile and/or vaginal application, intended to moisturize and lubricate, 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 condoms but is compatible with polyisoprene and polyurethane condoms.

Prescription Use_____ OR Over-The-Counter ____X____
Per 21CFR 801.109 Subpart D Per 21CFR 801.109 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, Gastro-Renal, and Urological Devices
510(k) Number K120650