

JUN 21 1988

K955648

## 510 (k) SUMMARY of SAFETY AND EFFECTIVENESS

### **Statement**

Information supporting claims of substantial equivalence, as defined under the Federal Food Drug and Cosmetic Act, with respect to safety and effectiveness is summarized below. For the convenience of the reviewer, this summary is formatted in accordance with the Agency's final rule..."510(k) Summaries and 510(k) Statements"(21CFR807) and can be used to provide a substantial equivalence summary to anyone requesting it from the Agency.

- **New Device's Name:** K-Y<sup>®</sup> Liquid Personal Lubricant
- **Predicate Device(s)'**: K-Y<sup>®</sup> Jelly Personal Lubricant, Johnson & Johnson  
ASTROGLIDE<sup>®</sup> Personal Lubricant, BioFilm Inc.

**Intended Use** - The K-Y<sup>®</sup> Liquid Personal Lubricant is an over-the-counter personal lubricant.

**Indications** - This device is indicated to enhance the comfort and ease of intimate activity with or without a latex condom. K-Y<sup>®</sup> Liquid Personal Lubricant can be safely applied directly to a genital body orifice or a latex condom. The product can be used inside condoms to facilitate application or outside for lubrication during intercourse.

**Device Description** - The K-Y<sup>®</sup> Liquid Personal Lubricant formula is non-sticky, non-staining, non-greasy and is compatible with latex condoms in laboratory testing. It is a water soluble clear, high viscosity gel-like liquid. Because it is water-soluble, K-Y<sup>®</sup> Liquid Personal Lubricant is easily rinsed off with water. The product is packaged in a convenient to use squeeze bottle with a flip-top cap.

**Technological Characteristics** - K-Y<sup>®</sup> Liquid Personal Lubricant is thoroughly tested and proven safe to use. It contains only United States Pharmacopeia (USP) or National Formulary (NF) ingredients all of which are listed as "generally recognized as safe" (GRAS), with the exception of Hydroxyethyl Cellulose (Natrosol 250H).

[Hydroxyethyl Cellulose is listed in the FDA's Inactive Ingredients Guide and has been safely used as an ingredient in the predicate device, K-Y<sup>®</sup> Jelly for many years. It is also an ingredient in many drug products e.g.: oral syrups, oral tablets, ophthalmic, and otic solutions.]

Laboratory testing demonstrated K-Y<sup>®</sup> Liquid Personal Lubricant to be compatible with latex condoms. The testing concluded that condoms treated with K-Y<sup>®</sup> Liquid Personal Lubricant and condoms that were not treated showed no substantial differences in mechanical properties.

K-Y<sup>®</sup> Liquid Personal Lubricant has been shown to be both non-staining and lubricating when compared to the predicate devices, K-Y<sup>®</sup> Jelly and ASTROGLIDE<sup>®</sup>. In 2 different studies conducted to evaluate these attributes, the K-Y<sup>®</sup> Liquid Personal Lubricant formulation was tested against the two predicate devices. The lubricating study showed that K-Y<sup>®</sup> Liquid Personal Lubricant was more lubricating than both K-Y<sup>®</sup> Jelly and ASTROGLIDE<sup>®</sup>. In the non-staining study, all of the devices had similar results with the predicate device, K-Y<sup>®</sup> Jelly showing the least amount of any staining (99% observation of no stain or very light staining) compared to the proposed device, K-Y<sup>®</sup> Liquid Personal Lubricant with 98%. ASTROGLIDE<sup>®</sup> was rated at 88%. Both predicate devices currently carry a claim of non-staining.

#### **Safety Testing**

Clinical Laboratory and Safety testing in humans and in animals demonstrated that K-Y<sup>®</sup> Liquid Personal Lubricant is safe and effective for its intended use.

#### **A) Clinical Dermal Irritation Study - Human Repeat Insult Patch Test**

A total of 105 subjects completed the entire study which was conducted comparing K-Y<sup>®</sup> Liquid Personal Lubricant and the predicate device, ASTROGLIDE<sup>®</sup>. Neither product showed significant evidence of primary irritation or allergic sensitization. There were no reactions during the induction series and only a single plus-minus reaction during the challenge phase.

#### **B) 10 -Day Rabbit Vaginal Irritation Study with K-Y<sup>®</sup> Liquid Personal Lubricant**

This study, which was conducted at an outside testing laboratory, showed that the proposed device does not exhibit the potential to produce significant irritation in rabbits when administered intravaginally for ten consecutive days.

#### **Substantial Equivalence**

K-Y<sup>®</sup> Liquid Personal Lubricant is substantially equivalent to other marketed predicate devices, namely ASTROGLIDE<sup>®</sup> and K-Y<sup>®</sup> Jelly. All of these products are sold over-the-counter and are indicated as personal lubricants. Laboratory tests comparing K-Y<sup>®</sup> Liquid Personal Lubricant to K-Y<sup>®</sup> Jelly and ASTROGLIDE<sup>®</sup> demonstrated these products to perform in a similar manner under similar conditions.

**Performance Data**

Consumer home use testing of K-Y<sup>®</sup> Liquid Personal Lubricant compared to the predicate device, ASTROGLIDE<sup>®</sup>, demonstrated that on virtually all individual characteristic, the majority of women did not have a preference between K-Y<sup>®</sup> Liquid Personal Lubricant and ASTROGLIDE<sup>®</sup>. Where preferences were indicated, they were split between K-Y<sup>®</sup> Liquid Personal Lubricant and ASTROGLIDE<sup>®</sup>, with each holding a few directional advantages over the other.

Based upon testing data and FDA's Own Substantial Equivalence Decision Process, K-Y<sup>®</sup> Liquid Personal Lubricant has been demonstrated to be a device which is safe and effective for its intended use.