K033776
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instead
women's reproductive health products

JUN 2 5 2004

Corporate Headquarters:
4370 La Jolla Village Drive, Suite 960
San Diego, CA 92122
Tel. 858.642.7515
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510K SUMMARY

This summary of 510K safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

The assigned 510K number is:_____

1. Submitter's Identification:

   Instead Inc.
   4370 La Jolla Village Drive,
   Suite 960
   San Diego, California 92122
   Telephone: 858-642-7515
   Facsimile: 858-623-6991

   Contact Person: Joe Pike, CEO/President

   Date of Summary: 11-18-03

2. Device Name: Instead Intimate Lubricant

3. Classification Name: Lubricant (21 CFR 884.5300)

4. Predicate Device:

   a. K982673 – The Just Between Us™ lubricant by Key West Fragrance & Cosmetic Factor.
   b. K983216 – CVS Personal Lubricant by San-Mar Laboratories.

5. Intended Use: Instead Intimate Lubricant is intended to enhance the comfort and ease of intimate activity and is compatible with latex and polyurethane condoms.

[illegible] Hutton Drive
Suite 307
Carrollton, Texas 75006
972.484.9333 tel
972.484.9336 fax
www.softcup.com

6. Device Description/ Comparison:

Instead Intimate Lubricant is a water-glycerin based lubricant that uses thickening agents for gel formation. No fragrances or petroleum-based chemicals are used in the formulation.

A comparison of the technological characteristics of the Instead Intimate Lubricant with the predicate devices (shown in the table below) substantiates the substantial equivalence of the Instead Intimate Lubricant to the predicate devices.

Table 1. Comparison of Technological Characteristics

Characteristic/ Feature	Instead Intimate Lubricant	The Just Between Us™ (K982673)	CVS Personal Lubricant (K983216)
Contains purified water	Yes	Yes	Yes
Contains glycerin	Yes	Yes	Yes
Contains thickening agents	Yes	Yes	Yes
Contains preservatives	Yes	Yes	Yes
Container Material	Plastic	Plastic	Plastic
Label Condom Compatible	Yes	Yes	Yes
Sterile	No	No	No

Non-clinical testing of the Instead Intimate Lubricant included measurement of bioadhesion, buffering capacity, effect on semen, viscosity and compatibility with latex and polyurethane condoms. Instead Intimate Lubricant had better bioadhesive properties, maintained its initial pH and viscosity better when mixed with semen than other lubricants tested. The testing with semen suggested that the Instead Intimate Lubricant may reduce sperm motility (Garg, S. 2001). Latex and polyurethane condoms were tested in accordance with ASTM D3492-02 after exposure to Instead Intimate Lubricant for up to 24 hours. No effect on condom performance was found.

In-vivo testing (penile and anal irritation) confirmed the biocompatibility of the Instead Intimate Lubricant. Additionally, a repeated dose vaginal irritation study in six women confirmed the biocompatibility of the Instead Intimate Lubricant (Amaral et al. 2000).

Amaral, E., et al. Study of the vaginal tolerance to acidform, an acid-buffering bioadhesive gel, Contraception, 60:361-366, 2000.

Garg, S., et al., Properties of a new acid-buffering bioadhesive vaginal formulation (Acidform), Contraception, 64:67-75, 2001.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

FEB 24 2014

Mr. Joe Pike
CEO/President
Instead, Inc.
4370 La Jolla Village Drive, Suite 960
SAN DIEGO, CA 92122

Re: K033776
Trade/Device Name: Instead Intimate Lubricant
Regulation Number: 21 CFR §884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated (Date on orig SE ltr): April 16, 2004
Received (Date on orig SE ltr): April 19, 2004

Dear Mr. Pike:

This letter corrects our substantially equivalent letter of June 25, 2004.

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 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. 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 -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

510k Number (if Known): K033776

Device Name: Instead Intimate Lubricant

Indications for Use:

Instead Intimate Lubricant is intended to enhance the comfort and ease of intimate activity and is compatible with latex and polyurethane condoms.

Prescription Use: _____ OR Over-the-Counter Use: X
(Per 21 CFR 801.109)

Concurrence of CFRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033776