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510K Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92

1. Submitters Identification:

CST Medical Ltd
Antrobus House 18 College Street
Petersfield Hants GU31 4AD UK

Contact Person: John Adcock
Regulatory Specialist

Date of Summary: May 5, 2005

2. Device Name: Vielle™ Lubricant

3. Classification Name: Lubricant (21 CFR 884.5300)

4. Predicate Device:

Instead, Inc.	Instead Intimate Lubricant	K033776
Qualis, Inc.	Personal Lubricating Gel	K041129

5. Intended Use:

Vielle™ personal lubricant is intended for personal lubrication, lubrication of a body orifice to facilitate use of diagnostic or therapeutic, to enhance condom use and for vaginal use.

6. Device Description/Comparison:

Vielle™ is a clear, water-soluble, silicone based gel. No fragrances or petroleum-based chemicals are used in the formulation.

A comparison of technological characteristics of the CST lubricant with predicate devices substantiates the substantial equivalence of the Vielle™ Lubricant to the predicate devices.

	CST Medical *Vielle*™ Lubricant	**Instead, Inc Instead Intimate Lubricant**	**Qualis, Inc. Personal Lubricating Gel**
Common Name	**Lubricant**	**Lubricant**	**Lubricant**
Product Code	**80 MMS**	**80 MMS**	**80 MMS**
Intended Use	**Personal**	**Personal**	**Personal**

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	Lubricating Gel	Lubricating Gel	Lubricating Gel
Indications for use	***Vielle*™ personal lubricant is intended for personal lubrication, lubrication of a body orifice to facilitate use of diagnostic or therapeutic, to enhance condom use and for vaginal use..**	**Personal Lubricating Gel is designed to enhance the ease and comfort of intimate activity and is compatible with latex condoms.**	**Personal Lubricating Gel is designed to enhance the ease and comfort of intimate activity and is compatible with latex condoms.**
Over the Counter Use	**YES**	**YES**	**YES**
Water-soluble	**YES**	**YES**	**YES**
Contains Preservatives	**NO-Product is inert & cannot support Microbial contamination.**	**YES**	**YES**
Latex compatible Tested	**YES**	**YES**	**YES**
Biocompatibility Tested	**YES**	**YES**	**YES**
Antimicrobial Tested	**YES**	**YES**	**YES**
Sterile	**NO**	**NO**	**NO**

Non-clinical testing of the Vielle™ Lubricant included compatibility testing with condoms and biocompatibility testing for irritation and sensitization.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 3 2006

CST Medical Ltd.
c/o Mr. E. J. Smith
E.J. Smith Associates
1676 Village Green, Suite A
CROFTON MD 21114

Re: K051288
Trade/Device Name: Vielle™ Lubricant
Regulation Number: 21 CFR §884.5300
Regulation Name: Condom
Product Code: HIS
Regulation Number: 21 CFR §880.6375
Regulation Name: Patient lubricant
Product Code: KMJ
Regulatory Class: II
Dated: January 5, 2006
Received: January 9, 2006

Dear Mr. Smith:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051288

Device Name: Vielle™ Lubricant

Classification Panel: 880.6375

Indications for Use:

Vielle™ personal lubricant is intended for personal lubrication, lubrication of a body orifice to facilitate use of diagnostic or therapeutic, to enhance condom use and for vaginal use.

Prescription Use_____ **And/Or** **Over the Counter Use** ____√____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K051288