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

September 16, 2015

Polichem S.A.
% Barry E Sands
President
RQMIS, Inc.
29 Water Street, Suite 305
Newburyport, MA 01950

Re: K143349
Trade/Device Name: Gynomunal
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: Class II
Product Code: NUC
Dated: August 18, 2015
Received: August 21, 2015

Dear Barry Sands,

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 Industry and Consumer Education 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" (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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education 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,

Herbert P. Lerner -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143349

Device Name

Gynomunal Vaginal Gel

Indications for Use *(Describe)*

Gynomunal 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 and with polyisoprene condoms, but not with polyurethane 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

Polichem, S.A. 's Gynomunal

Sponsor:	Manufacturer:	Polichem, S.A. Via Senago 42D 6912 – Lugano-Pazzallo Switzerland
	Official Contact:	Barry E. Sands
	Phone:	978-358-7307
	Fax:	978-378-7384
	Date Prepared:	September 8, 2015

Device Name: Gynomunal

Common Name: Personal Lubricant

Classification Name: Condom (21 CFR 884.5300)

Product Code: NUC

Predicate Device: Me Again Long Lasting Vaginal Moisturizer (K112217)

Indications for Use

Gynomunal 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 and with polyisoprene condoms, but not with polyurethane condoms.

Technological Characteristics

Gynomunal is a non-sterile, water-based, ivory to slightly yellow personal lubricant with a shelf-life of 36 months.

Gynomunal device specifications include color, odor, pH, viscosity, osmolality, antimicrobial effectiveness (Compliance with USP <51>), and microbiological quality (Compliance with USP <61>, <62>, and <1111>).

Color	Homogeneous, Translucent Gel (Ivory, to slight yellow)

Odor	Characteristic
pH	5.5-6.5
Viscosity	45,000-65,000 mPa*s
Osmolality	2,000 -3,000 mOsmol/Kg
Antimicrobial Effectiveness	Complies to USP <51>
Total Aerobic Microbial Counts	<100 cfu/g
Total Yeast and Mold counts	<10 cfu/g
Microbial Absence	*P. aeruginosa* *S. aureus* *C. albicans*

Performance Data

Gynomunal was demonstrated to be biocompatible utilizing the following tests:

- ISO 10993-5:2009—Cytotoxicity
- ISO 10993-10:2010—Vaginal Irritation
- ISO 10993-10:2010—Guinea Pig Maximization Sensitization
- ISO 10993-11:2006—Acute Systemic Toxicity

Gynomunal was demonstrated to maintain its specifications throughout its 36 month shelf-life through real time and accelerated testing.

To substantiate the revised claim of condom compatibility Polichem SA commissioned an independent laboratory to conduct condom compatibility studies with **Gynomunal** according to ASTM D7661 – 10 Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms. The results were reviewed within the context and requirements of ISO 4074 - Natural Latex Rubber Condoms - Requirements And Test Methods. Laboratory testing concluded that Gynomunal is compatible with natural rubber latex and polyisoprene condoms.

Substantial Equivalence

Gynomunal is as safe and effective as the **Me Again Long Lasting Vaginal Moisturizer**. **Gynomunal** has the same intended use and principle of operation, and similar indications and technological characteristics as the predicate device. The minor technological differences between the **Gynomunal** and the predicate device raise no new types of questions of safety or effectiveness. Performance data provided in this premarket notification demonstrate that the **Gynomunal** is as safe and effective as **Me Again Long Lasting Vaginal Moisturizer, and that**

Gynomunal is compatible with natural rubber latex and polyisoprene condoms**.** Thus, **Gynomunal** is substantially equivalent to the predicate.