March 1, 2024

Tyros Biopharma Inc.
% Roshana Ahmed
President
Quaras, LLC
2101 Camino Rey
Fullerton, California 92833

Re: K232040
Trade/Device Name: Gynatrof®
Regulation Number: 21 CFR 884.5300
Regulation Name: Lubricant, Personal
Regulatory Class: II
Product Code: NUC
Dated: February 2, 2024
Received: February 2, 2024

Dear Roshana Ahmed:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See

the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Monica D. Garcia -S

Monica D. Garcia, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
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Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232040

Device Name

Gynatrof®

Indications for Use *(Describe)*

Gynatrof 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.

Gynatrof is compatible with natural rubber latex, polyisoprene condoms and 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary – K232040

I. Submitter

Tyros Biopharma Inc.
4702 Louis-B.-Mayer
Suite 305
Laval, QC H7P 0L9
Canada

Contact Person: Anthony Gouvoussis, CEO
Phone: 514-447-1485
Date Prepared: February 29, 2024

II. Subject Device Information

Device Proprietary Name:	Gynatrof®
Common or Usual Name:	Personal Lubricant
Regulation Name:	Condom
Regulation Number:	21 CFR 884.5300
Product Code:	NUC (Lubricant, Personal)
Device Classification	Class II

III. Predicate Device Information

Device Proprietary Name:	Gynomunal
510(k) number	K143349
Manufacturer	Polichem SA
Regulation Number:	21 CFR 884.5300
Product Code:	NUC (Lubricant, Personal)
Device Classification	Class II

The predicate device has not been subject to a design-related recall.

IV. Device Description

Gynatrof® is a personal lubricant intended to moisturize, lubricate, and enhance the ease and comfort of intimate sexual activity as well as supplement the body's natural lubrication. The product is supplied with a reusable, non-sterile, single-patient use applicator. Gynatrof® is compatible with natural rubber latex, polyisoprene, and polyurethane condoms. The product is intended for over-the-counter use.

The device formulation consists of Aqua/Water, Hydroxyethylcellulose, Lactic Acid, Polysorbate 20, Potassium Sorbate, Sodium Hyaluronate, Sodium Levulinate, Tocopherol. Gynatrof® is supplied in a 50 mL white tube; each tube contains sufficient product for 20 applications using the reusable applicator.

The device specifications are listed in the table below:

Table 1 - Device Specifications

Parameter	Test Method	Specification
Appearance	Visual inspection	Off white to pale yellow gel
Odor	Olfactory	Characteristic
pH (25°C)	USP <791>	5.00 ± 0.50
Viscosity	USP <912>	67,500 – 100,000 cps (T4- 3rpm)
Osmolality	USP <785>	120 - 250 mOsm/kg
Specific Gravity (25°C)	USP <841>	0.9000 – 1.1000
Antimicrobial Effectiveness	USP <51>	Bacteria - Not less than 2.0 log reduction from the initial count at 14 days, and no increase from the 14 days' count at 28 days. Yeast and Molds - No increase from the initial calculated count at 14 and 28 days. No increase is defined as not more than 0.5 log unit higher than the previous value measured.
Total Microbial Count	USP <61>	< 100 CFU/g
Fungal/Yeast/Mold Limits	USP <61>	< 10 CFU/g
Absence of Pathogenic Organisms	USP <62>	Absent (*Pseudomonas Aeruginosa, Staphylococcus Aureus, E. Coli, Salmonella, C. Albicans)*

V. Indications for Use

Gynatrof® 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.
Gynatrof® is compatible with natural rubber latex, polyisoprene condoms and polyurethane condoms.

VI. Comparison of Intended Use and Technological Characteristics with the Predicate Device

Table 2 : Technological Comparison between Subject Device – Gynatrof and Predicate device- Gynomunal		
Feature	**Gynatrof (Subject device)**	**Gynomunal (Predicate Device)**
Device Classification Name	Lubricant, Personal	Lubricant, Personal
Product Code	NUC	NUC
Indications for Use	Gynatrof is a personal lubricant, for vaginal and/or penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. Gynatrof is compatible with natural rubber latex, polyisoprene condoms, and polyurethane condoms.	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 condoms
Water soluble	Yes	Yes
Contains water	Yes	Yes
Primary ingredients	Aqua/Water, Hydroxyethyl cellulose, Lactic Acid, Polysorbate 20, Potassium Sorbate, Sodium Hyaluronate, Sodium Levulinate, Tocopherol.	Purified water, propylene glycol, denatured ethanol, hop extract (Humulus lupulus), soy lecithin (E322), carbomer, methyl-4-hydroxybenzoate (E219), cholesterol, imidazolidinylurea, sodium edetate, hyaluronic acid, propyl-4-hydroxybenzoate (E217), tocopherol acetate (vitamin E)
pH	4.50 to 5.50	5.5 to 6.5
Osmolality	120 - 250 mOsm/kg	2,000 - 3,000 mOsmol/Kg
Over the counter use	Yes	Yes
Sterile	No	No
Condom Compatibility	Natural Rubber Latex, Polyisoprene, Polyurethane	Natural Rubber Latex
Biocompatibility Tested	Yes	Yes
Antimicrobial Tested (USP <51>, USP <61>, USP <62>)	Yes	Yes
Shelf life	12 months	36 months

The subject and predicate device have similar indications for use statements and have the same intended use (i.e., provides lubrication during intimate sexual activity).

The subject and predicate devices are both water-based, non-sterile lubricants with differences in technological characteristics, including different formulations and device specifications. The different technological characteristics of the subject device do not raise different questions of safety and effectiveness.

VII. Summary of Non-Clinical Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility: Biocompatibility studies were performed in accordance with the 2020 FDA guidance Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices- Part 1: Evaluation and testing within a risk management process. " The following testing was conducted:

- Cytotoxicity (ISO 10993-5:2009)
- Sensitization (ISO 10993-10:2010)
- Vaginal Irritation (ISO 10993-10:2010)
- Acute Systemic Toxicity (ISO 10993-11:2017)

The results of testing demonstrated the subject device is non-cytotoxic, non-sensitizing, non-irritating, and non-systemically toxic.

Condom Compatibility: The compatibility of the subject devices with natural rubber latex, polyisoprene and polyurethane condoms was evaluated in accordance with ASTM D7661-18 - Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms. The results of testing demonstrated that the subject device is compatible with natural rubber latex, polyisoprene, and polyurethane condoms.

Shelf Life: The subject device has a shelf-life of 12-months based on the results of a real-time aging study. The shelf-life study evaluated all device specifications listed in Table 1.

VIII. Conclusion

The results of the performance testing described above demonstrate that Gynatrof® is as safe and effective as the predicate device and supports a determination of substantial equivalence.