November 10, 2020

Peptonic Medical AB
% Jane Campbell
President
J & D Campbell Associates, Inc.
164 Hammock Ave.
Pawleys Island, South Carolina 29585

Re: K200098
Trade/Device Name: VagiVital Aktivgel
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: September 30, 2020
Received: October 13, 2020

Dear Jane Campbell:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200098

Device Name
VagiVital Aktivgel

Indications for Use *(Describe)*
VagiVital Aktivgel is a personal lubricant for 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 polyisoprene condoms. This product is not compatible with natural rubber latex 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.

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510(K) SUMMARY – K200098

Applicant:	Peptonic Medical AB Gustavslundsvägen 143 SE-167 51 Bromma Sweden Phone: +46 8 530 20 110
Contact Person:	Dan Markusson Chief Operating Officer Gustavslundsvägen 143 SE-167 51 Bromma Sweden
Date Prepared:	November 5, 2020
Proprietary Name:	VagiVital Aktivgel
Common Name:	Personal Lubricant
Regulation Number:	21 CFR 884.5300
Regulation Name:	Condom
Product Code:	NUC (Lubricant, Personal)
Regulatory Class:	II

Predicate Device:

- HyaloGYN Hydrating Gel, Fidia Farmaceutici, S.p.A. - K150883

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

Device description

VagiVital Aktivgel is a water-based personal lubricant containing water, hypromellose, benzoic acid, lactic acid, and sodium hydroxide. VagiVital Aktivgel is provided in a 36 ml aluminum tube and may be packaged together with a reusable applicator.

Device specifications are listed in the table below:

Parameter	Specification
Appearance/Color	Clear gel with fine visible particles
Odor	Odorless
pH	3.6-4.0
Viscosity per USP <912>	13800-75000 s
Osmolality per USP <785>	32-150 mOsmol/kg
Antimicrobial Effectiveness per USP <51>	Category 2 per USP <51>
Total Microbial Count per USP <61>	<100 cfu/ml
Fungal/Yeast/Mold Limits per USP <61>	<10 cfu/ ml
Absence of Pathogenic Organisms per USP <62> *Pseudomonas aeruginosa* *Staphylococcus aureous* *Candida albicans*	Absent

Indications for use

VagiVital Aktivgel is a personal lubricant for 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 polyisoprene condoms. This product is not compatible with natural rubber latex and polyurethane condoms.

Comparison of Intended Use and Technological Characteristics of the subject and predicate device:

A comparison of the intended use and technological features of the subject and predicate devices is provided in the table below:

Device & Predicate Device(s):	**VagiVital Aktivgel Subject Device (K200098)**	**HyloGyn Hydrating Gel Predicate Device (K150883)**

General Device Characteristics		
Indications for Use	VagiVital Aktivgel is a personal lubricant for 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 polyisoprene condoms. This product is not compatible with natural rubber latex and polyurethane condoms.	HyaloGYN is a personal lubricant for vaginal application intended to mositurize and lubricate, to enhance the ease and comfort to intimate sexual activity and supplement for body's natural lubrication. This product is compatible with polyisoprene condoms.
Primary Ingredients	Water S-lactic acid Sodium Hydroxide 2M solution Benzoic Acid Hydroxypropyl methylcellulose	Hyaluronic Acid (Hydeal-D) Propylene glycol Carbopol 974P (carbomer) Sodium hydroxide Purified water
Condom compatibility	Compatible with polyisoprene condoms	Compatible with polyisoprene condoms
Base Type	Water	Water
Biocompatibility Tested	Yes	Yes
Antimicrobial Tested	Yes	Yes

The subject and predicate device have similar indications for use statements and have the same intended use.

The subject device and predicate device have different technological characteristics, including different formulations. The differences in technological characteristics between the subject and predicate devices do not raise different questions of safety and effectiveness.

Summary of Performance Data:

Shelf life:

VagiVital Aktivgel has a shelf-life of 24 months in accordance with the results of an accelerated aging and real-time stability study. Results from testing demonstrated that the device can maintain its specifications (as shown in Table 1) over the duration of its shelf-life.

Biocompatibility:

Biocompatibility studies were performed in accordance with the 2016 FDA guidance document "Use of International Standard ISO 10993-1, Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process" and ISO 10993- 1:2009 as follows:

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

The biocompatibility testing demonstrated that the subject device is non-cytotoxic, non-irritating, non-sensitizing, and not systemically toxic.

Condom Compatibility:

VagiVital Aktivgel was tested in accordance with ASTM D7661-10 "S*tandard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms"* and was determined to be compatible with polyisoprene condoms. It was determined not to be compatible with natural rubber latex and polyurethane condoms.

Conclusion:

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