Ultrast, Inc.
% Howard Levine
President
3286 Balsam Street
OCEANSIDE NY 11572

December 22, 2021

Re: K211691
Trade/Device Name: Ultrast Gel
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: Class II
Product Code: MUI
Dated: November 24, 2021
Received: November 24, 2021

Dear Howard Levine:

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 and Part 809); 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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K211691

Device Name
Ultrast Gel

Indications for Use *(Describe)*

Ultrast Gel is an in vivo biocompatible and bioexcretable sterile couplant intended for use as a scanning gel in surgical procedures, biopsies and similar sterile applications.
Ultrast Gel is used to couple sound waves between the patient and medical imaging electronic transducers during intracavitary medical diagnostic ultrasound imaging procedures, transcutaneous ultrasound image guided biopsy and aspiration, intracavity ultrasound imaging, and gel infusion sonography.
Ultrast Gel is unit dose packaged, sterilized and intended for use in all diagnostic ultrasound procedures that currently use an ultrasound coupling gel or other fluid, alone or in combination with a transducer cover, where sterility, in vivo biocompatibility and bioelimination are required.
ULTRAST Gel is available by prescription only for use by healthcare providers trained in performing the indicated procedure.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the Ultrast Gel is provided below.

1. SUBMITTER

Applicant:	Ultrast, Inc. Tel: 516-606-1754
Contact:	Howard Levine President Tel. 516-606-1754 Email. hll@well.com
Submission Correspondent:	Howard Levine President Tel. 516-606-1754 Email. hll@well.com

Date Prepared: June 1, 2021

2. DEVICE

Device Trade Name:	Ultrast Gel
Device Common Name:	Sterile ultrasound gel
Classification Name	Diagnostic ultrasonic transducer (21 CFR 892.1570)
Regulatory Class:	Class II
Product Code:	MUI

3. PREDICATE DEVICE

Predicate Device: Farco-Pharma GmbH; Lubricano Sterile Gel (K083358)

4. DEVICE DESCRIPTION

The Ultrast Gel device, manufactured for Ultrast, Inc. is a phase changing hydrogel ultrasound coupling agent comprised of hydroxy-propylcellulose, sodium chloride, sodium citrate, and water. HCl may be added to adjust pH if necessary. The gel is viscous at room temperature, but subsequently liquefies as its temperature rises and reaches body temperature. In addition to general lubricating/coupling properties, the gel may be instilled in the uterine cavity through a standard intrauterine insemination (IUI) catheter to provide excellent ultrasonographic visualizations, after which point it liquifies and passes out of the uterine cavity.

The gel is contained in a single use 5cc capped syringe enclosed in a peel pouch to maintain sterility.

5. INTENDED USE/INDICATIONS FOR USE

Ultrast Gel is an in vivo biocompatible and bioexcretable sterile couplant intended for use as a scanning gel in surgical procedures, biopsies and similar sterile applications.

Ultrast Gel is used to couple sound waves between the patient and medical imaging electronic transducers during intracavitary medical diagnostic ultrasound imaging procedures, transcutaneous ultrasound image guided biopsy and aspiration, intracavity ultrasound imaging, and gel infusion sonography.

Ultrast Gel is unit dose packaged, sterilized and intended for use in all diagnostic ultrasound procedures that currently use an ultrasound coupling gel or other fluid, alone or in combination with a transducer cover, where sterility, in vivo biocompatibility and bioelimination are required.

ULTRAST Gel is available by prescription only for use by healthcare providers trained in performing the indicated procedure.

6. SUBSTANTIAL EQUIVALENCE

Comparison of Indications

The indications for use are nearly identical to the predicate.

Subject device Indication for Use:

> Ultrast Gel is an in vivo biocompatible and bioexcretable sterile couplant intended for use as a scanning gel in surgical procedures, biopsies and similar sterile applications.
>
> Ultrast Gel is used to couple sound waves between the patient and medical imaging electronic transducers during intracavitary medical diagnostic ultrasound imaging procedures, transcutaneous ultrasound image guided biopsy and aspiration, intracavity ultrasound imaging, and gel infusion sonography.
>
> Ultrast Gel is unit dose packaged, sterilized and intended for use in all diagnostic ultrasound procedures that currently use an ultrasound coupling gel or other fluid, alone or in combination with a transducer cover, where sterility, in vivo biocompatibility and bioelimination are required.

Predicate device Indications for Use:

> Lubricano is an in vivo biocompatible and bioexcretable sterile couplant intended for use as a scanning gel in surgical procedures, biopsies and similar sterile applications.
>
> Lubricano is used to couple sound waves between the patient and medical imaging electronic transducers during intracavitary medical diagnostic ultrasound imaging procedures, such as transcutaneous ultrasound image guided biopsy and aspiration, intracavity ultrasound imaging, and gel infusion sonography.
>
> Lubricano is unit dose packaged, sterilized and intended for use in all diagnostic ultrasound procedures that currently use an ultrasound coupling gel or other fluid, alone or in

combination with a transducer cover, where sterility, in vivo biocompatibility and bioelimination are required.

Technological Comparisons

The table below compares the key technological feature of the subject devices to the predicate device (Lubricano Sterile Gel, K083358).

Table 1: Technological Comparison

	Proposed Device	**Predicate Device**
510(k) Number	TBD	K083358
Applicant	Ultrast, Inc.	Farco-Pharma GmbH
Device Name	Ultrast Gel	Lubricano Sterile Gel
Classification Regulation	21 CFR 892.1570	21 CFR 892.1570
Product Code	MUI – Media, Coupling, Ultrasound	MUI – Media, Coupling, Ultrasound
Indications for Use	Ultrast Gel is an in vivo biocompatible and bioexcretable sterile couplant intended for use as a scanning gel in surgical procedures, biopsies and similar sterile applications. Ultrast Gel is used to couple sound waves between the patient and medical imaging electronic transducers during intracavitary medical diagnostic ultrasound imaging procedures, transcutaneous ultrasound image guided biopsy and aspiration, intracavity ultrasound imaging, and gel infusion sonography. Ultrast Gel is unit dose packaged, sterilized and intended for use in all diagnostic ultrasound procedures that currently use an ultrasound coupling gel or other fluid, alone or in combination with a transducer cover, where sterility, in vivo biocompatibility and bioelimination are required.	Lubricano is an in vivo biocompatible and bioexcretable sterile couplant intended for use as a scanning gel in surgical procedures, biopsies and similar sterile applications. Lubricano is used to couple sound waves between the patient and medical imaging electronic transducers during intraoperative and intracavitary medical diagnostic ultrasound imaging procedures, such as transcutaneous ultrasound image guided biopsy and aspiration, intraoperative ultrasound imaging, intracavity ultrasound imaging, and gel infusion sonography. Lubricano is unit dose packaged, sterilized and intended for use in all diagnostic ultrasound procedures that currently use an ultrasound coupling gel or other fluid, alone or in combination with a transducer cover, where sterility, in vivo biocompatibility and bioelimination are required.
Containing Unit	Syringe	Syringe
Composition	Hydroxypropylcellulose, sodium chloride, sodium citrate, and water	Hydroxyethylcellulose, Glycerol, Purified Water
Sterile	Yes – Moist Heat	Yes – Moist Heat
pH Range	6.5-8.5	5.0-7.5
Viscosity	90,000-140,000 cps	Greater than 1800 mPas

	Proposed Device	Predicate Device
Density	1.010 – 1.030 g/cm3	1.018 – 1.028 g/cm3
Acoustic Impedance	1.574 @ 4 MHz 1.579 @ 7 MHz 1.579@ 10 MHz	1.61 Mrayl (estimated)
Speed of Sound	1513 m/sec @4 MHZ (25.6 °C) 1518 m/sec @7 MHZ (25.6 °C) 1518 m/sec @10 MHZ (25.6 °C)	1532 m/s
Sound Attenuation	0.02 (dB/cm-MHz)	0.0023f 2.17 dB/cm-MHzn
Biocompatibility	Meets ISO-10993 Requirements, addressed through testing or risk assessment: Cytotoxicity Sensitization Irritation Acute Systemic Toxicity Pyrogenicity	Meets ISO-10993 Requirements Passed testing for: Cytotoxicity Sensitization Irritation
Labeled Use	Prescription Use	Prescription Use

6.1. Comparison of Technological Characteristics and Substantial Equivalence Conclusion

The proposed device has identical an intended use and identical indications for use compared to the predicate, as such there are no issues of substantial equivalence based on the proposed use. When examining technological characteristics, the proposed device is very similar to the predicate. Its major difference is the phase-changing characteristics that allow for easier removal. This phase change takes place after the ultrasound procedure and therefore leads to no significant questions of safety and effectiveness compared to the predicate. That is, the feature is described in the instructions for use and is supported by performance testing to demonstrate it works as intended. The minor differences in formulation are supported by the acoustic testing and biocompatibility testing. Other performance testing supporting substantial equivalence includes sterilization validation and shelf-life/stability evaluation.

Based on the detailed comparison between the predicate devices and the subject device, the Ultrast Gel can be found substantially equivalent to the predicate device.

7. PERFORAMNCE DATA

Biocompatibility Testing

Ultrast Gel is an Implant Device contacting Tissue/Bone for a Limited Contact Duration. As such, biocompatibility testing was carried out according to the requirements in the following standards:

- ISO 10993-1:2018, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ISO10993-5:2009, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010, Biological Evaluation of Medical Devices Part 10: Tests for Irritation and Skin Sensitization
- ISO 10993-11:2017, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity

Test results support that the Ultrast Gel device is biocompatible for its intended use and contact duration.

Electrical safety and electromagnetic compatibility (EMC)

Not applicable. The subject device is a software-only device. It contains no electric components, generates no electrical emissions, and uses no electrical energy of any type.

Software Verification and Validation Testing

Not applicable. The device contains no software.

Bench Testing

To establish the substantial equivalence of Ultrast Gel, bench testing was conducted to validate the performance of the device. The following tests were conducted:

- Appearance
- pH Level Testing
- Phase Change/Viscosity Testing
- Syringe Force Testing
- Acoustic Testing

The following tests were also conducted:

- Bubble Leak Testing
- Package Peel Testing
- Pouch Dye Penetration Testing

The results of the bench testing support that technological characteristics of the proposed device are substantially equivalent to the predicate device.

Animal Testing

Not applicable. Animal studies are not necessary to establish the substantial equivalence of this device.

Clinical Data

Not applicable. Clinical studies are not necessary to establish the substantial equivalence of this device.

8. CONCLUSION

Like the predicate device, performance testing supports that the Ultrast Gel device biocompatible and meets requirements for performance testing, acoustic properties, sterility, and shelf life. Based on the detailed comparison between the predicate device and the subject device, the performance testing and conformance with applicable standards, Ultrast Gel can be found substantially equivalent to the predicate device.