December 16, 2020

HertART ApS
Ann-Catherine Ericson
RA Manager
Gustaf Werners gata 2
Västra Frölunda, SE-421 32
Sweden

Re: K201213
Trade/Device Name: Pasteur Pipette 3mL, Pasteur Pipette 1mL
Regulation Number: 21 CFR§ 884.6160
Regulation Name: Assisted Reproduction Labware
Regulatory Class: II
Product Code: MQK
Dated: November 2, 2020
Received: November 18, 2020

Dear Ann-Catherine Ericson:

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,

for 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)*
K201213

Device Name
Pasteur Pipette 3mL, Pasteur Pipette 1 mL

Indications for Use *(Describe)*
The Pasteur Pipettes are intended for handling and transferring of liquids, media and gametes during assisted reproductive technology procedures.

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.

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510(k) Summary – K201213

Date prepared: December 7, 2020

Applicant: HertART ApS
Gustaf Werners gata 2
SE-421 32 Västra Frölunda
Sweden
Phone: +46 (0) 708 22 80 28
Email: psvensson@vitrolife.com
Fax: +46 (0) 31 721 80 90

Contact Person: Ann-Catherine Ericson
RA Manager
Phone: +46 (0) 701 64 88 36
Email: aericson@vitrolife.com

1 Device Information

Trade Name: Pasteur Pipette 3mL, Pasteur Pipette 1mL
Common name: Pasteur Pipettes
Regulation number: 21 CFR 884.6160
Regulation name: Assisted Reproduction Labware
Product code: MQK (Labware, Assisted Reproduction)
Class: II

1.1 Predicate Device:

K000915 - Pasteur Pipet - Sterile 9, Pasteur Pipet - Sterile 5 3/4, Models 16-PP-9, 16-PP-5.75, Humagen Fertility Diagnostics, Inc.

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

2 Device description

The Pasteur Pipettes are radiation-sterilized, single use, transparent low-density polyethylene pipettes intended for handling and transferring of liquids, media and gametes during assisted reproductive technology (ART) procedures. The pipettes are provided in two sizes, 1 mL (Model 16201) and 3 mL (Model 16202). Each pipette includes an integrated bulb end that is used to aspirate and expel liquid, media and gamete to and from the device. The pipettes also include a molded volume scale along the body of the pipette. The volume scale only provides an estimate of the aspirated volume. The pipettes will not come in contact with the human body during use.

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2.1 Indications for Use

The Pasteur Pipettes are intended for handling and transferring of liquids, media and gametes during assisted reproductive technology procedures.

3 Comparison of Subject and Predicate Device Intended Use and Technological Characteristics

Attribute	Subject Device Pasteur Pipette K201213	Predicate Device Pasteur Pipet K000915	Differences
Indications for Use	The Pasteur Pipettes are intended for handling and transferring of liquids, media and gametes during assisted reproductive technology procedures.	Pasteur pipets are a general laboratory pipette to be used anytime there is a need to move fluid or cells. They may also be used to "denuda" ova prior to an ivf procedure.	The indications for the subject and predicate devices are not identical. Both the predicate and subject devices are indicated for handling of gametes, media, and other fluids; however, the predicate is also indicated for use in denuding oocytes. This difference only represents a more limited use of the subject devices as compared to the predicate and does not impact the overall intended use of the devices (handling and transferring fluids, media, and gametes used in assisted reproduction procedures), which are the same.
Design	Single piece molded Pasteur pipette	Glass Pasteur pipette to be used with separate bulb	**Different**: There are differences in the designs of the subject and predicate devices; however, they do not raise different questions of safety and effectiveness (S&E).
Material	Low density polyethylene	Borosilicate glass	**Different:** The subject and predicate device materials are not the same. Differences in materials do not raise different questions of S&E.
Size	15.2 cm	5.75″ (14.6cm) and 9″ (22.9cm)	**Different**: Both the 1 mL and 3 mL subject devices have the same length, which is different than the predicate that is provided in two lengths. Differences in length do not raise different questions of S&E.
Volume capacity	1 mL and 3 mL	Unknown	**Different:** The volume capacity of the predicate is not known; however, differences in volume capacity do not raise different questions of S&E.

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Packaging	Peel open pouch consisting of PE/PA-film and a BOPET / Adhesive / EZ Peel® Sealant 500 pouches of one pipette each packed in a cardboard box	Material of pouches not known. 30 pouches of three pipettes each packed in boxes of 90 (30 pouches)	**Different:** Packaging is different for the subject device as compared to the predicate device. Differences in packaging do not raise different questions of S&E.
Sterile	Yes - Gamma irradiation	Yes -Dry heat	**Different:** Different sterilization methods are used for the subject and predicate devices. Differences in sterilization methods do not raise different questions of S&E.
Shelf-life	2 years	Unknown	**Different:** The shelf-life of the predicate is not known; however, differences in shelf-life do not raise different questions of S&E.
Endotoxin testing (LAL)	≤ 0.25 EU/device	LAL tested, limits not specified	**Different:** Endotoxin testing was conducted on the predicate device; however, the acceptance specification is not known. Differences in endotoxin testing do not raise different questions of S&E.
Mouse Embryo Assay (MEA)	≥ 80% 1-cell expanded blastocyst within 96 hours	MEA tested, limits not specified	**Different:** MEA testing was conducted on the predicate device; however, the acceptance specification is not known. Differences in MEA testing do not raise different questions of S&E.

As stated in the table, the subject and predicate devices have similar indications for use statements and have the same intended use (i.e., handling and transferring fluids, media, and gametes used in assisted reproduction procedures).

The subject and predicate devices have differences in technological characteristics, including their design, materials, packaging, etc. As stated in the table, the differences in technological characteristics between the subject and predicate devices do not raise different questions of safety and effectiveness.

4 Non-clinical Performance Data

4.1 Sterile validation

The subject devices are gamma irradiation sterilized. The sterilization process and validation methods were done in accordance with ISO 11137-1:2006 and ISO 11137-2:2013. The sterilization assurance level of the subject devices is 10^{-6}.

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4.2 Package Validation

Verification of the ability of device packaging to maintain a sterile barrier over the two-year shelf-life of the device was assessed using the following methods:

- Seal strength testing according to ASTM F88/F88M-15 “Standard Test Method for Seal Strength of Flexible Barrier Materials”
- Dye penetration test according to ASTM F3039-15 “Standard Test Method for Detecting Leaks in Nonporous Packaging or Flexible Barrier Materials by Dye Penetration”
- Visual inspection according to ASTM F1886/F1886M-16 “Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection”

Testing demonstrated that the sterile barrier was maintained over the two-year shelf-life.

4.3 Transport Testing

Simulated transport testing was conducted to demonstrate the ability of device packaging to withstand the rigors of shipping. Testing was performed in accordance with ASTM D4169-16.

4.4 Stability and Shelf life

The proposed shelf-life of the subject device is two years. The following tests were conducted on newly manufactured devices and devices after accelerated aging in accordance with ASTM F1980-16:

- Mouse Embryo Assay (MEA (1-cell, expanded blastocyst within 96 hours) ≤80%)
- Endotoxin testing per USP<85> (≤0.25 EU/device)
- Visual inspection (no scratches or discolorization)
- Testing to ensure liquid can be aspirated and maintained within the device
- Volume marker validation testing

5 Conclusions

The results of the testing described above demonstrate that the Pasteur Pipette 1mL and Pasteur Pipette 3mL are as safe and effective as the predicate and supports a determination of substantial equivalence.