July 17, 2020

Origio a/s, a CooperSurgical Company
Monika Bak, Ph.D.
Regulatory Affairs Officer
Knardrupvej 2
Måløv 2760
Denmark

Re: K200680
Trade/Device Name: SynVitro® Hyadase
Regulation Number: 21 CFR§ 884.6180
Regulation Name: Reproductive Media and Supplements
Regulatory Class: II
Product Code: MQL
Dated: June 11, 2020
Received: June 19, 2020

Dear Monika Bak:

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.
Acting 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K200680

Device Name
SynVitro® Hyadase

Indications for Use *(Describe)*
SynVitro® Hyadase is for the removal of the cumulus complex and corona radiata surrounding the oocyte in preparation for ICSI.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

a CooperSurgical Company

510(k) SUMMARY

K200680 - SynVitro® Hyadase

510(k) Submitter

Company Name: ORIGIO a/s
Company Address: Knardrupvej 2
2760 Måløv,
Denmark

Contact

Name: Monika Bak, PhD
Telephone: +45 60190206
Fax: +45 4679 0300
E-mail: monika.bak@coopersurgical.com

Date Prepared: July 15, 2020

Device Identification

Trade name: SynVitro® Hyadase
Common Name: Reproductive Media
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive Media and Supplements
Product Code: MQL (Media, Reproductive)
Regulatory Class: Class II

Predicate Device Information

K031228 - SynVitro® Hyadase

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

Device Description

SynVitro® Hyadase is a modified version of the prior cleared SynVitro® Hyadase device and is used for removal of cumulus and *corona radiata* cells surrounding the oocytes (denudation) prior to intracytoplasmic sperm injection (ICSI).

SynVitro® Hyadase is a clear non-viscous hyaluronidase enzyme solution contained in a 2 ml transparent plastic bottles (containing 1 ml solution) with caps and provided in cardboard boxes containing five bottles. This product has a one-year shelf-life when stored as recommended and can be used for up to seven days after opening.

Indications for Use

SynVitro® Hyadase is for the removal of the cumulus complex and *corona radiata* surrounding the oocyte in preparation for ICSI.

a CooperSurgical Company

SUBSTANTIAL EQUIVALENCE DISCUSSION

Table 1: Substantial Equivalence Comparison

Attribute	K200680 Subject Device: SynVitro® Hyadase	K031228 Predicate Device: SynVitro® Hyadase	Comparison
Manufacturer	ORIGIO a/s	ORIGIO a/s (formerly MediCult a/s)	Same
Indications for Use	SynVitro® Hyadase is for the removal of the cumulus complex and *corona radiata* surrounding the oocyte in preparation for ICSI.	For the removal of the cumulus complex and *corona radiata* surrounding the oocyte in preparation for ICSI.	Same
Product Design	Clear non-viscous solution contained in 2 ml transparent plastic bottles (containing 1 ml solution) with caps, with five bottles provided per box.	Clear non-viscous solution contained in 2 ml transparent plastic bottles (containing 1 ml solution) with caps, with five bottles provided per box.	Same
Formulation	• Hyaluronidase 80 IU/ml (non-bovine source) • Glucose • Sodium pyruvate • Calcium chloride • Magnesium sulphate • Sodium chloride • HEPES	• Hyaluronidase 80 IU/ml (non-bovine source) • ART supplement • Glucose • Sodium pyruvate • Calcium chloride • Magnesium sulphate • Sodium chloride • Sodium bicarbonate • HEPES	Different
pH	7.150-7.449	7.150-7.449	Same
Osmolality	272-288 mOsm/kg	272-288 mOsm/kg	Same
Endotoxin	≤0.5 EU/ml	Meets requirements per USP	Different
Hyaluronidase activity	80 IU/ml	80 IU/ml	Same
Mouse Embryo Assay	One-cell: ≥80% developed to the blastocyst stage within 96 hours after a 15-second exposure to SynVitro® Hyadase	One-cell: ≥80% developed to the blastocyst stage within 96 hours after a 15-second exposure to SynVitro® Hyadase	Same
Shelf Life	7 days (Open Vial) 52 weeks shelf life	Single use (Open vial) 15 weeks shelf life	Different

The subject and predicate devices have the same indications for use/intended use for removal of cumulus complex and *corona radiata* cells surrounding the oocyte in preparation for ICSI. In addition, the subject and predicate devices have the same hyaluronidase activity and specifications for pH, mouse embryo assay (MEA), and osmolality. However, differences exist in formulation,

origio a CooperSurgical Company

endotoxin, and device shelf-life. These differences do not raise different questions of safety and effectiveness as compared to the predicate device.

NON-CLINICAL PERFORMANCE TESTING

As part of demonstrating substantial equivalence to the predicate, a risk analysis was completed to identify the risks associated with the SynVitro® Hyadase formulation changes and shelf life claims. Verification testing was conducted to evaluate the modifications. The following tests associated with the device modifications were performed on the subject device according to methods and acceptance criteria outlined in the predicate device (K031228):

- pH testing was conducted per USP <791> (acceptance criterion: pH 7.150-7.449)
- Osmolality testing was conducted per USP <785> (acceptance criterion: 272-288 mOsm/kg)
- Aseptic Processing Validation was conducted per ISO 13408-1:2008 and ISO 13408-2:2018
- Sterility testing was conducted per USP <71> (acceptance criterion: no growth)
- Endotoxin testing was conducted per USP <85> (acceptance criterion: ≤ 0.5 EU/ml)
- Mouse embryo assay (MEA): One-cell mouse embryos were exposed to test article for 15 seconds, followed by a 96-hr culture. For a valid assay it is required that at least 80% of the one-cell stage control embryos develop to blastocysts stage within 96 hours. (acceptance criterion: One-cell: ≥80% developed to the blastocyst stage within 96 hours after a 15-second exposure to SynVitro® Hyadase)
- Hyaluronidase enzyme activity – measured by incubation of SynVitro® Hyadase with hyaluronic acid and assessment of turbidity of the resulting sample using a spectrophotometer at 640 nm. (acceptance criterion: 40-120 IU/ml)
- Shelf-life testing was conducted to ensure that the following product specifications are met at time zero, at the end of the shelf-life (52 weeks), and after seven days of simulated vial opening:
  - pH
  - Osmolality
  - One-cell MEA
  - Endotoxin concentration
  - Sterility testing
  - Hyaluronidase activity

CONCLUSION

The subject and predicate device have the same intended use and comparable technological characteristics. The differences in technological characteristics between the subject and predicate devices do not raise different questions of safety and effectiveness. The performance data demonstrate that the subject device is substantially equivalent to the predicate device.