DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 9, 2017

ORIGIO a/s
Tove Kjaer
Director, Corporate Regulatory Affairs
Knardrupvej 2
Maaloev, 2760
Denmark

Re: K161547
Trade/Device Name: Transem and EchoGen™ Embryo Transfer Catheters
Regulation Number: 21 CFR§ 884.6110
Regulation Name: Assisted Reproduction Catheters
Regulatory Class: II
Product Code: MQF
Dated: February 10, 2017
Received: February 13, 2017

Dear Tove Kjaer:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Joyce M. Whang -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161547

Device Name
Transem and EchoGen™ Embryo Transfer Catheters

Indications for Use *(Describe)*
The Transem and EchoGen™ are catheters with angled or spherical tips for embryo transfer into the uterine cavity in the treatment of infertility.

The Transem Stylets are intended to assist the insertion of the Transem or EchoGen™ catheters where the passage through the cervix is impeded.

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

Transem and EchoGen™ Embryo Transfer Catheters
510(k) Summary (K161547)

I. SUBMITTER

Name:	**ORIGIO a/s**
Address:	Knardrupvej 2 2760 Måløv Denmark
Contact Person:	Tove Kjær Director, Corporate Regulatory Affairs Telephone: +45 4679 0220 Fax: +45 4679 0300 Email: tkjaer@origio.com
Date of Preparation	March 8, 2017

II. SUBJECT DEVICE

Name of Device:	Transem and EchoGen™ Embryo Transfer Catheters
Common or Usual Name:	Embryo Transfer Catheters, Stylets
Classification Number:	21 CFR 884.6110
Classification Name:	Assisted Reproduction Catheters
Regulatory Class:	II
Product Code:	MQF (Catheters, Assisted Reproduction)
Included model numbers:	TSET25SA, TSET25SAO, TSET24SAS, TSET24SASO, TSS1520, TSS1823, TSS2025, TSET25SAEG, TSET25SAOEG, TSET24SASEG, TSET24SASOEG

III. PREDICATE DEVICE

Trade Name:	Wallace (Sure View) Embryo Replacement Catheter and Trial Transfer Catheter
Manufacturer:	Portex, Ltd.
510(k):	K033084

The predicate device was subject to a design-related recall in 2013. However, the recall status for the predicate device is completed, and the predicate device is currently marketed.

origio
a CooperSurgical Company

IV. DEVICE DESCRIPTION

The Transem and EchoGen™ are Embryo Transfer Catheters with various angled or spherical tips and various lengths. The EchoGen™ variants are designed to be visible under ultrasound imaging. Stylets to aid in the insertion of the embryo catheters are also available. The product variants covered in this 510(k) include the following:

Trade name	***Catheter type***	***Code***	***Description***
Transem	Angled tip	TSET25SA TSET25SAO	Transem Angled 25 cm Transem Angled O* 25 cm
	Spherical tip	TSET24SAS TSET24SASO	Transem Spherical 24 cm Transem Spherical O* 24 cm
	Stylets	TSS1520 TSS1823 TSS2025	Transem Stylet 15 cm Transem Stylet 18 cm Transem Stylet 20 cm
EchoGen™	Angled tip	TSET25SAEG TSET25SAOEG	EchoGen™ Angled 25 cm EchoGen™ Angled O* 25 cm
	Spherical tip	TSET24SASEG TSET24SASOEG	EchoGen™ Spherical 24 cm EchoGen™ Spherical O* 24 cm

*includes obturator

Key specifications for the Transem and EchoGen™ Embryo Transfer Catheters are listed in the table below.

Aspect	***Subject Device***
Packaging type	Blister pack
Sterility assurance level	SAL 10^{-6}
Sterilization method	Irradiation
Reprocessing	Single use
Shelf life	1.3 years
Endotoxins	≤ 1.25 EU/device
Mouse Embryo Assay	≥80% blastocyst rate at 96 hr (1-cell test)

V. INDICATIONS FOR USE

The Transem and EchoGen™ are catheters with angled or spherical tips for embryo transfer into the uterine cavity in the treatment of infertility.

The Transem Stylets are intended to assist the insertion of the Transem or EchoGen™ catheters where the passage through the cervix is impeded.

origio a CooperSurgical Company

VI. INTENDED USE AND TECHNOLOGY COMPARISON WITH THE PREDICATE DEVICE

Intended Use

The indication for use statements for the subject and predicate devices are shown in the table below.

Aspect	*Subject Device (K161547)*	*Predicate Device (K033084)*
Indications for use	The Transem and EchoGen™ are catheters with angled or spherical tips for embryo transfer into the uterine cavity in the treatment of infertility. The Transem Stylets are intended to assist the insertion of the Transem or EchoGen™ catheters where the passage through the cervix is impeded.	Embryo Replacement Catheters are sterile, single-use devices for ultrasound guided introduction of embryos into the uterine cavity following in vitro fertilization. Trial transfer catheters are sterile, single-use devices for determining whether the cervix is passable for a Wallace embryo replacement catheter.

The subject and predicate devices have the same intended use - transfering embryos into the uterine cavity during in vitro fertilization procedures. The subject device includes the Transem Stylet, which is intended to assist insertion of the catheters by maintaining rigidity of the device. While the use of a stylet is not included in the predicate device Indications for Use statement, the inclusion of the stylet does not represent a new intended use for the device. The predicate device indication includes a trial transfer catheter, used to determine whether the cervix is passable. The subject device does not contain a trial catheter; however, the lack of a trial catheter does not change the intended use of the subject device.

Technology

In the following tables, the technological features and performance specification of the subject device are compared to the predicate device.

Aspect	*Subject Device (K161547)*	*Predicate Device (K033084)*
Materials	Stainless steel Plastics (thermoplastic elastomers, polyethylene, polypropylene) Ink	Stainless steel Plastics (types not publicly available) Ink
Dimensions** - Working lengths - Forming of tip	 24/25 cm Spherical/Angled	 18/23 cm Straight/Angled

origio
a CooperSurgical Company

- Bulb tip - Inner catheter I.D. - Inner catheter O.D. - Outer catheter O.D.	Yes* 0.50*/0.77 mm 1.00*/1.47 mm 2.15*/2.65 mm	No 0.76 mm 1.50 mm 2.30 mm
Stylet	15/18/20 cm	Not present
Other characteristics - Echogenic tip - Echogenic principle	 Yes (EchoGen™ models) Metallic marker band	 Yes (Sureview & Surepro models) Extruded air bubbles

*: Models with spherical tips

**: The only difference between the Transem and EchoGen™ catheters is the inclusion of an echogenic marker. Therefore, the dimensions listed for the subject device apply to both the Transem and EchoGen™ catheters.

The technological characteristics of the subject device are different – the subject device has different material components, dimensions, echogenic marker materials, and includes a stylet to help maintain rigidity during insertion. However, different types of safety or effectiveness questions are not raised by these differences in technological characteristics.

VII. PERFORMANCE DATA

Biocompatibility testing

Transem and EchoGen™ were tested for cytotoxicity according to ISO 10993-5:2009, sensitization according to ISO 10993-10:2010 and vaginal irritation according to ISO 10993-10:2010. The results showed the device is not cytotoxic, not sensitizing and a non-irritant.

Sterilization and Shelf-life

The sterilization of Transem and EchoGen™ has been validated according to ISO 11137-2:2006. The shelf-life has been established through real-time and accelerated testing according to standards ISO 11607-1:2006 and ASTM F1980-07. The following parameters were assessed during shelf life testing:

- Air resistance
- Tensile strength
- Dimensional characteristics
- Sterility
- Endotoxin (Limulus Amebocyte Lysate test per USP<85>)
- Mouse Embryo Assay (MEA)
- Package integrity (peel strength, visual inspection for damage, label integrity, and contamination)

Bench Testing

Bench testing included the physical properties of Transem and EchoGen™ (air resistance, tensile strength, dimensional verification), performance characteristics (sterility, endotoxin and embryotoxicity [MEA]), and echogenic marker assessments (mounting accuracy, pull force to remove), flow restriction, and ultrasound visibility assessment.

a CooperSurgical Company

VIII. CONCLUSIONS

The results of the testing described above demonstrate that the Transem and EchoGen™ Embryo Transfer Catheters are as safe and effective as the predicate device and supports a determination of substantial equivalence.