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510(k) Summary – EmbryoScope time-lapse incubator (Version D) and EmbryoViewer software

Administrative information

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Date of summary: 8-August-2014

Device name and predicate device name

Trade name	Common name	Device	Class	CFR Reference	Product code	Predicate device K number
EmbryoScope® time-lapse incubator (Version D) and EmbryoViewer™ software	EmbryoScope time-lapse system	Assisted reproduction accessories and Picture archiving and communications system	II	884.6120	MQG	113075

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Indications for Use EmbryoScope time-lapse incubator (Version D) and EmbryoViewer software

The EmbryoScope® time-lapse incubator (version D) provides an environment with controlled temperature, CO2 (and other gasses) for the development of embryos. This model has an integrated inverted microscope and imaging system for embryo viewing. Device use is limited to five days (120 hr) covering the time from post-fertilization to day 5 of development.

The EmbryoViewer™ software is an optional accessory software package for use in displaying, comparing, storing, and transferring images generated by the EmbryoScope® time-lapse incubator (Version D). The software includes a user annotation function for capturing information on embryo development parameters as well as a user-defined modeling function, which allows the user to combine annotated information on embryo development parameters to aid in embryo selection. The EmbryoViewer™ software does not control any hardware components in the EmbryoScope® time-lapse incubator (Version D).

Device description EmbryoScope® time-lapse incubator (Version D)

The EmbryoScope® time-lapse incubator is a tri-gas incubator, which acquires a series of unattended measurements on individual embryos during their development. The measurements include: time-lapse microscopy at multiple focal planes and logging of incubation conditions. Separate processing units control the incubation environment and data acquisition to ensure safe and reliable operation. Up to 72 embryos (6 EmbryoSlide® culture dishes with 12 embryos in each culture dish) can be incubated simultaneously.

Indications for use EmbryoScope® time-lapse incubator (Version D)

	EmbryoScope	EmbryoScope (K113075)
Indications for use	The EmbryoScope® time-lapse incubator (Version D) provides an environment with controlled temperature, CO2 (and other gases) for the development of embryos. This model has an integrated inverted microscope and imaging system for embryo viewing. Device use is limited to five days (120 hr) covering the time from post-fertilization to day 5 of development.	The EmbryoScope (Version D) provides an environment with controlled temperature, CO2 (and other gases) for the development of embryos. This model has an integrated inverted microscope and imaging system for embryo viewing. Device use is limited to five days (120 hr) covering the time from post-fertilization to day 5 of development.

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Summary of Performance testing EmbryoScope® time-lapse incubator (Version D)

For the EmbryoScope time-lapse incubator software and gas system component (EGS), the test cases that have been performed to verify and validate requirements are an evaluation of tests performed on previous version of the EmbryoScope time-lapse incubator software and gas system component (GB), with addition of tests related to new features described in this submission. Test results have been evaluated and it has been concluded to accept the test results; the EmbryoScope time-lapse incubator is substantially equivalent to the predicate device.

Comparison to Predicate Device EmbryoScope® time-lapse incubator (Version D)

	EmbryoScope	EmbryoScope (K113075)
Indications for use	The EmbryoScope® time-lapse incubator (Version D) provides an environment with controlled temperature, CO2 (and other gases) for the development of embryos. This model has an integrated inverted microscope and imaging system for embryo viewing. Device use is limited to five days (120 hr) covering the time from post-fertilization to day 5 of development.	The EmbryoScope (Version D) provides an environment with controlled temperature, CO2 (and other gases) for the development of embryos. This model has an integrated inverted microscope and imaging system for embryo viewing. Device use is limited to five days (120 hr) covering the time from post-fertilization to day 5 of development.
Design features	Gas system component (EGS) providing an environment with controlled temperature, CO_2 (and other gases) for the development of embryos. An integrated inverted microscope and imaging system for embryo viewing. IR-cut off filter enabling reduced exposure times and increased image acquisition frequency	Gas system component (GB) providing an environment with controlled temperature, CO_2 (and other gases) for the development of embryos. An integrated inverted microscope and imaging system for embryo viewing.

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	Treatment ID should be specified for all EmbryoSlide culture dishes Integrated computer running Microsoft Windows 7 Load door LEDs (red/green) indicating the status of the load door lock Optional barcode reader	 Integrated computer running Microsoft Windows Vista
Non-Clinical Tests performed for Determination of Substantial Equivalence	The tests described in the software test plan for the EmbryoScope time-lapse incubator software and gas system component (EGS), derived from the Software Requirements Specification and technical specification, are an evaluation of tests performed on previous version on the EmbryoScope time-lapse incubator software and gas system component (GB), with addition of tests related to new features described in this submission Underwent and passed electrical safety electromagnetic compatibility environmental and operating performance testing in accordance with IEC 60601-1:2005	 Underwent and passed electrical safety electromagnetic compatibility environmental and operating performance testing in accordance with IEC 60601-1:1998
Clinical Tests performed	No clinical testing was performed. Tests with and without mouse embryos have been performed to confirm that the performance of the gas	Clinical data show that the EmbryoScope (Version D) performs according to the intended use of the device.

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	system component (EGS) is equivalent to the gas system component (GB) in the predicate device. No adverse effects of image acquisition were observed.	 No adverse effects of image acquisition were observed.

The indications for use for the EmbryoScope time-lapse incubator have not changed as a consequence of the change in design features described above. To the name EmbryoScope, the description *time-lapse incubator* has been added.

The components in the EmbryoScope time-lapse incubator are considered equivalent to the components in the predicate device included in the submission K113075.

Incubation conditions and image quality are not adversely affected by the above changes.

The addition of the features described above to the EmbryoScope time-lapse incubator does not raise new types of safety and effectiveness questions.

Device description EmbryoViewer™ software

The purpose of the EmbryoViewer™ software is to assist the embryologist in selecting embryos for transfer or freezing. This is obtained by allowing the embryologist to inspect high-resolution time-lapse images of embryo development, to use detailed annotation tools and to inspect the running conditions of the EmbryoScope® time-lapse system.

The EmbryoViewer™ software does not perform any diagnostics, but only shows data from the EmbryoScope® time-lapse system and data entered by the user.

The EmbryoViewer™ software provides:

- High-resolution time-lapse images of single embryos
- Embryo annotation tools which assist the user in selecting embryos
- Option to design a set of models that can be used for scoring embryos
- Inspection of incubation details, e.g. temperature and gas conditions
- Export of data for statistical analysis

The EmbryoViewer™ software is an optional accessory package to the EmbryoScope® time-lapse system. The time-lapse system provides a controlled culture environment that allows continuous monitoring and observation of up to 72 embryos at a time.

The data from the EmbryoScope® time-lapse system can be seen in the EmbryoViewer™ software. This includes embryo images, incubation details, alarms, log files and other

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instrument parameters. The EmbryoViewer™ software can be used to review and compare synchronized time-lapse movies of various embryos.

In addition, the EmbryoViewer™ software contains a database which enables the user to annotate time-lapse images for e.g. cleavage times, fragmentation, multinucleation, pronuclei and other characteristics used for selecting embryos for transfer. Annotations are saved in the database and can be exported to an Excel file for statistical analysis.

The EmbryoViewer™ software also enables input of patient details, treatment data and outcome data. This data is stored in the database and can be exported to an Excel file complete with annotations.

Indications for use EmbryoViewer™ software

	EmbryoViewer	EmbryoViewer (K113075)
Indications for Use	The EmbryoScope® time-lapse system (version D) provides an environment with controlled temperature, CO2 (and other gasses) for the development of embryos. This model has an integrated inverted microscope and imaging system for embryo viewing. Device use is limited to five days (120 hr) covering the time from post-fertilization to day 5 of development. The EmbryoViewer™ software is an optional accessory software package for use in displaying, comparing, storing, and transferring images generated by the EmbryoScope® time-lapse incubator (Version D). The software includes a user annotation function for capturing information on embryo development parameters as well as a user-defined modeling function, which allows the user to combine annotated	EmbryoViewer is an optional accessory software package for use in displaying, comparing, storing, and transferring EmbryoScope (Version D) generated images. The software includes a user annotation function for capturing information on embryo development parameters, treatment data, and outcome data. The EmbryoViewer software does not control any hardware components in the EmbryoScope (Version D) device.

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	information on embryo development parameters to aid in embryo selection. The EmbryoViewer™ software does not control any hardware components in the EmbryoScope® time-lapse incubator (Version D).	

Summary of Performance testing EmbryoViewer™ software

For the EmbryoViewer software, the test cases that have been performed to verify and validate requirements are an evaluation of tests performed on previous version on the EmbryoViewer software, with addition of tests related to new features described in this submission. Test results have been evaluated and it has been concluded to accept the test results; the EmbryoViewer software is as safe, as effective and performs as well or better than the EmbryoViewer software included in the submission K113075.

Comparison to Predicate Device EmbryoViewer™ software

Substantial equivalence is claimed to legally marketed device and accessory covered by K113075, the EmbryoViewer software from Unisense FertiliTech A/S.

	EmbryoViewer	EmbryoViewer (K113075)
Indications for Use	The EmbryoScope® time-lapse system (version D) provides an environment with controlled temperature, CO2 (and other gasses) for the development of embryos. This model has an integrated inverted microscope and imaging system for embryo viewing. Device use is limited to five days (120 hr) covering the time from post-fertilization to day 5 of development. The EmbryoViewer™ software is an optional accessory software package for use in displaying,	EmbryoViewer is an optional accessory software package for use in displaying, comparing, storing, and transferring EmbryoScope (Version D) generated images. The software includes a user annotation function for capturing information on embryo development parameters, treatment data, and outcome data. The EmbryoViewer software does not control any hardware components in the EmbryoScope (Version D) device.

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	comparing, storing, and transferring images generated by the EmbryoScope® time-lapse incubator (Version D). The software includes a user annotation function for capturing information on embryo development parameters as well as a user-defined modeling function, which allows the user to combine annotated information on embryo development parameters to aid in embryo selection. The EmbryoViewer™ software does not control any hardware components in the EmbryoScope® time-lapse incubator (Version D).	
Design features	Displaying, comparing, storing, and transferring EmbryoScope time-lapse incubator generated images and an annotation function. In the Model Designer, the user can define models applied in the Compare & Select view where embryos are listed together with the score from the applied model	Displaying, comparing, storing, and transferring EmbryoScope (Version D) generated images and an annotation function.
Non-Clinical Tests performed for Determination of Substantial Equivalence	The EmbryoViewer software is fulfilling the requirements of the IEC 62304 standard according to software testing. The tests described in the software test plan for the EmbryoViewer software, derived from the Software Requirements Specification, are an evaluation of tests performed on previous version on the EmbryoViewer	The EmbryoViewer software is fulfilling the requirements of the IEC 62304 standard according to software testing.

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	software, with addition of tests related to new features described in this submission	
Clinical Tests performed	This section does not apply. No clinical testing was performed	This section does not apply. No clinical testing was performed

The addition of the features models and Compare & Select result in a new Indications for Use for the EmbryoViewer software.

The update of the EmbryoViewer software has no impact on incubation conditions in the EmbryoScope time-lapse incubator.The new features models and Compare & Select in the EmbryoViewer software does not introduce or require changes to the EmbryoScope time-lapse incubator.

As the EmbryoViewer software does not control any functions on the EmbryoScope time-lapse incubator it can not affect the operation of the EmbryoScope time-lapse incubator. The addition of the features models and Compare & Select to the EmbryoViewer software does not raise new types of safety and effectiveness questions.

Conclusion

The subject device is substantially equivalent to the predicate device.

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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

August 8, 2014

Unisense FertiliTech A/S
Henrik Wahlgren
QA & RA Manager
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Re: K133712
Trade/Device Name: EmbryoScope time-lapse incubator (Version D)
and EmbryoViewer software
Regulation Number: 21 CFR§ 884.6120
Regulation Name: Assisted reproduction accessories
Regulatory Class: II
Product Code: MQG
Dated: July 14, 2014
Received: July 17, 2014

Dear Henrik Wahlgren,

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,

Herbert P. Lerner -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

Indications for Use

510(k) Number (if known): K133712

Device Name: EmbryoScope time-lapse incubator (Version D) and EmbryoViewer software

Indications For Use:

The EmbryoScope® time-lapse incubator (version D) provides an environment with controlled temperature, CO2 (and other gasses) for the development of embryos. This model has an integrated inverted microscope and imaging system for embryo viewing. Device use is limited to five days (120 hr) covering the time from post-fertilization to day 5 of development.

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Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Herbert P. Lerner -S
2014.08.08 13:09:58 -04'00'