January 14, 2020

CooperSurgical Inc.
Kyle Hooper
Regulatory Affairs Associate
95 Corporate Drive
Trumbull, CT 06611

Re: K191020
Trade/Device Name: G210 InviCell Plus with SignipHy™ pH Monitoring System
Regulation Number: 21 CFR 884.6120
Regulation Name: Assisted Reproduction Accessories
Regulatory Class: II
Product Code: PUB
Dated: December 12, 2019
Received: December 13, 2019

Dear Kyle Hooper:

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191020

Device Name
G210 InviCell Plus with SignipHy™ pH Monitoring System

Indications for Use *(Describe)*
The G210 InviCell Plus with SignipHy™ pH Monitoring System is a bench-top incubator that is intended to provide a controlled environment at or near body temperature and gas levels (CO2, O2, and N2) for the development of gametes and/or embryos during In Vitro Fertilization (IVF) / Assisted Reproductive Technology (ART) treatments.

The G210 InviCell Plus with SignipHy™ pH Monitoring System includes an accessory for pH monitoring of surrogate samples of bicarbonate-based culture media used for ART 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

K191020

Submitter Information

Company Name: CooperSurgical Inc.
Company Address: 95 Corporate Drive
Trumbull, CT 06611 USA

Contact Person: Kyle Hooper
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Date Prepared: January 13, 2020

Device Information

Trade Name: G210 InviCell Plus with SignipHy™ pH Monitoring System
Common Name: Embryo Incubator with pH monitoring
Regulation Number: 21 CFR 884.6120
Regulation Name: Assisted Reproduction Accessories
Product Code: PUB (Accessory, Assisted Reproduction, Exempt)
Regulatory Class: II

Predicate Device Information

Trade Name: BT37 Incubator (510(k) number: K121566)
Common Name: IVF Incubator
Classification Name: Accessory, Assisted Reproduction (21 CFR 884.6120)
Product Code: MQG

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

Device Description

The G210 InviCell Plus with SignipHy™ pH Monitoring System is an assisted reproduction incubator that includes an accessory pH monitoring feature. The incubator component of this device (G210 Invicell) is regulated under 21 CFR 884.6120, product code PBH (exempt). The incubator includes 10 incubation chambers and one larger preparation chamber that is used for the equilibration of plates/oil before use. The tri-gas incubator provides a controlled environment (temperature, $CO_2/O_2/N_2$) for gametes and embryos in the incubation chambers.

The pH monitoring feature of the G210 InviCell Plus with SignipHy™ pH Monitoring System is controlled separately and does not impact the operation or incubator functions of the device. The SignipHy™ pH Monitoring System consists of the following components:

- SignipHy™ TrakPod – An LED-based, optical pH measurement instrument. The SignipHy TrakPod is physically supported within the chassis of the incubator and allows monitoring of one incubator chamber. It is a USB connected fluorescent measurement device with a fiber optic cable and fixture that connects to the SignipHy sv^2 Sensor inside an incubator chamber. The SignipHy TrakPod and SignipHy sv^2 Sensor together detect the pH of a liquid sample.

- SignipHy™ sv^2 Sensor – The SignipHy sv^2 Sensor is a single-use, polystyrene, ethylene oxide sterilized vessel that is loaded with a sample of bicarbonate-buffered assisted reproduction technology (ART) media with a pH between 6.8 and 7.2 for pH tracking. The bottom of the sensor includes a membrane that is impregnated with a dye that is affected by the pH of the media sample. The sensor fits into the SignipHy TrakPod fiber optic fixture located in an incubation chamber. SignipHy sv^2 Sensors can be used for measuring pH at one-minute intervals for three days or 30-minute intervals for seven days.

- SignipHy™TrakStation – A tablet computer running proprietary software that initiates pH readings, displays results, and stores pH measurement data over time. Up to eight SignipHy TrakPods can be connected to a single SignipHy TrakStation.

- SignipHy™ qc^2 Alignment Tool - A fluorescent reference device for use in system alignment and quality control.

To make a pH measurement, the SignipHy TrakPod sends green light flashes (peak 518 nm) through the fiber optic fixture. The dye in the membrane reacts by sending back flashes of light at a different wavelength (peak 600 nm). The SignipHy TrakPod reads this result and calculates the pH of the media sample that is then displayed on and stored in the SignipHy™TrakStation.

Indications for Use

The G210 InviCell Plus with SignipHy™ pH Monitoring System is a bench-top incubator that is intended to provide a controlled environment at or near body temperature and gas levels (CO2, O2, and N2) for the development of gametes and/or embryos during In Vitro Fertilization (IVF) / Assisted Reproductive Technology (ART) treatments.

The G210 InviCell Plus with SignipHy™ pH Monitoring System includes an accessory for pH monitoring of surrogate samples of bicarbonate-based culture media used for ART procedures.

Table 1 provides a comparison of the indications for use and technological characteristics of the subject device and predicate device.

Table 1: Subject and Predicate Device Comparison

Attribute	**Subject** G210 InviCell Plus with SignipHy™ pH Monitoring System	**Predicate** BT37 Incubator	**Discussion**
510(k) Number	K191020	K121566	Not Applicable
Manufacturer	CooperSurgical, Inc.	Planer Plc	Not Applicable
Indications for Use	The G210 InviCell Plus with SignipHy™ pH Monitoring System is a bench-top incubator that is intended to provide a controlled environment at or near body temperature and gas levels (CO2, O2, and N2) for the development of gametes and/or embryos during In Vitro Fertilization (IVF) / Assisted Reproductive Technology (ART) treatments. The G210 InviCell Plus with SignipHy™ pH Monitoring System includes an accessory for pH monitoring of surrogate samples of bicarbonate-based culture media used for ART procedures.	The Planer BT37 Incubator is intended to be used to provide an environment with controlled temperature at or near body temperature, $C0_2$. 0_2 and N_2 gases, and elevated humidity for the development of gametes and embryos during in vitro fertilization (IVF) / assisted reproductive technology (ART) treatments	**Different:** The subject and predicate devices are both indicated for maintaining temperature and gas concentrations sufficient to support gametes and embryos. The predicate device indication also lists maintenance of humidity within the chamber. Lack of humidity control in the subject device does impact the overall intended use of the device (maintaining environment for ART procedures). FDA has cleared humidified and non-humidified ART incubators. The subject device indications for use also lists the ability of the device to measure pH of bicarbonate-based media within the incubator. The pH information is given to laboratory personnel to provide additional information on the environmental conditions within the incubator, as pH changes are influenced by CO_2 concentrations. Although the predicate device does not include a pH measurement function, the overall intended use of the subject and predicate devices is the same (i.e., providing a controlled environment for gamete and embryo development in vitro).

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Attribute	Subject G210 InviCell Plus with SignipHy™ pH Monitoring System	Predicate BT37 Incubator	Discussion
General Design	Bench-top incubator with 10 incubation chambers and one preparation chamber	Bench-top incubator with 2 incubation chambers	**Different:** The subject device has more incubation chambers and an additional chamber to equilibrate plates/oil before use. This difference does not raise different questions of safety and effectiveness (S&E).
Gas Supply Type	Internally regulated mixture of CO_2, O_2 and N_2	Premixed blend of 6% CO_2, 5% O_2, 89% N_2	**Different:** The subject and predicate devices use different mechanisms to control gas concentrations in incubator chambers. This difference does not raise different S&E questions.
Gas Supply Pressure	0.5-1.0 bar (50 – 100 kPa)	150 kPa +/- 15 kPa	**Different:** The subject and predicate devices have different gas supply pressures based on the different gas supply/control methods. This difference does not raise different S&E questions.
Gas flow rate capability	1 l/h CO_2 & 5 l/h N_2	0 mL/min to 450 ml/min. Normal bleed set to 15 ml/min and purge at 180 ml/min for 3 minutes. Flows fully adjustable in 1 ml/min increments	**Different:** The subject and predicate devices have different gas flow rates based on the different gas supply/control methods. This difference does not raise different S&E questions.
Gas flow rate accuracy	CO_2: 1.5 l/h N_2: 7 l/h	±10% or ± 3% ml/min	**Different:** The flow rate accuracy is different for the subject and predicate devices that use different gas supply types. Differences in flow rate accuracy do not raise different questions of S&E.
Gas flow pattern	Constant	Pulsed or non-pulsed (constant) flow pattern.	**Different:** The subject device does not include a pulsed flow mode. This difference does not raise different S&E questions.
Incubation Chamber Heating	Resistive heating foil – bottom, sides and lid of each chamber	Not known	**Different:** The heating mechanism used in the predicate device is not known. However, differences in heating methods do not raise different S&E questions.
Chamber temperature capability	Ambient to 42.9 ˚C	5 ˚C above ambient to 40 ˚C	**Similar**
Chamber temperature accuracy	± 0.2 ˚C calibration point	± 0.2 ˚C calibration point	**Same**

Attribute	Subject G210 InviCell Plus with SignipHy™ pH Monitoring System	Predicate BT37 Incubator	Discussion
Humidification system	No	Yes	**Different:** The subject device does not include a humidification feature. This difference does not raise different S&E questions. FDA has cleared both humidified and non-humidified ART incubators.
pH Measurement Function	Device includes a pH measurement system that includes a non-contact fiber optic pH probe and sensor that holds a representative media within one incubation chamber, while a separate display showing pH information is on the exterior of the incubator.	No	**Different:** The predicate device does not include a pH measurement system. The inclusion of the pH system in one incubation chamber provides additional information on the incubation environment. This difference does not raise different questions of S&E as compared to the predicate (e.g., the ability to aid in maintaining an appropriate culture environment, materials do not raise potential embryotoxicity concerns, etc.).

As shown in the table above, the subject and predicate devices have different indications for use statements; however, the intended uses of the predicate and subject devices are the same (i.e., providing a controlled environment for gamete and embryo development in vitro during assisted reproduction technology procedures).

In regards to technological characteristics, the subject and predicate devices have similarities (e.g., more than one incubation chamber, chamber temperature accuracy, etc.); however, as noted in the table above, technological differences were identified between the subject and predicate devices (e.g., pH monitoring system, gas supply, gas management, total number of incubation chambers, humidification of chambers, etc.). As stated in the table, the technological differences between the subject and predicate devices do not raise different questions of safety and effectiveness.

Non-Clinical Performance Testing

The following performance data were provided in support of the substantial equivalence determination:

- Sterilization Validation of SignipHy™ sv^2 Sensors:
  - ISO 11135:2014 Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices
  - AAMI TIR28:2016 Product Adoption and Process Equivalence for Ethylene Oxide Sterilization
  - Residual testing was not conducted, as the sensor is non-patient and non-gamete/embryo contacting.

- Shelf-Life of SignipHy™ sv^2 Sensors:
  - Package integrity testing at the end of shelf-life in real-time aged samples after shipping/distribution:
    - Visual Inspection per ASTM F1886/F1886M-16
    - Seal Strength per ASTM F88/F88M-15
    - Dye penetration per ASTM F1929-15
  - SignipHy™ sv^2 Sensor Performance at the end of shelf-life in real-time aged samples after shipping/distribution:
    - Comparison of subject device pH measurements to gold standard (blood gas analyzer) at a single time point.
    - Assessment of pH under worst-case conditions (samples collected at one minute intervals for three days) as compared to gold standard (blood gas analyzer).

- Reprocessing: Cleaning and disinfection validation testing conducted in accordance with the FDA guidance document, "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling."

- Electrical Safety, Electromagnetic Compatibility (EMC), and Wireless Technology:
  - Electrical Safety Testing:
    - IEC 61010 2-010: 2014 (Third Edition)
    - IEC 61010-2-101: 2015 (Second Edition)
  - EMC Testing:
    - IEC 61326-1:2012
  - Wireless Technology: Information provided in accordance with the FDA guidance document, "Radio Frequency Wireless Technology in Medical Devices.

- Software and Cybersecurity:
  - Software documentation in accordance with FDA guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" to support device software with a minor level of concern.
  - Cybersecurity information in accordance with FDA guidance document "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices."

- pH Monitoring Validation Testing:
    - The submission included testing to support the ability of the device to measure pH in bicarbonate-based ART media. Testing showed that the device met all specifications for each parameter assessed below:
        - Linearity
        - Stability
        - Precision
        - Accuracy
        - Interfering substances

- Light Safety: Light energy exposure testing was performed to assess the potential for light toxicity associated with pH measurements taken under worst-case exposure conditions (samples taken every minute – total light exposure of 8.8 seconds/day). The results showed that the light wavelengths and worst-case light energy exposure duration did not raise safety concerns as compared to conventional imaging using standard laboratory ART imaging procedures.

- Mouse Embryo Assay (MEA): Testing was performed to assess the impact of the device (SignipHy TrakPod and SignipHy sv^2 Sensor) when in operation under worst-case conditions (samples taken every minute for 96h). The results of testing met the acceptance specification of "1-Cell MEA: ≥90% blastocysts at 96h."

- Incubator Performance Testing: The incubator component of this device is 510(k) exempt and remains unchanged from that currently marketed. The additional pH monitoring system is separate from the incubator and does not impact its function. Therefore, performance testing on the incubator was not requested.

Conclusion

The results of the testing described above demonstrate that the subject G210 InviCell Plus with SignipHy™ pH Monitoring System is substantially equivalent to the predicate device.