November 4, 2022

TMRW Life Sciences, Inc.
Christina Miracle
VP, QARA
250 Hudson Street, 6th Floor
New York, NY 10013

Re: K221086
Trade/Device Name: CryoRobot Select System
Regulation Number: 21 CFR§ 884.6120
Regulation Name: Assisted Reproduction Accessories
Regulatory Class: II
Product Code: QUJ
Dated: October 3, 2022
Received: October 3, 2022

Dear Christina Miracle:

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,

Michael T. Bailey -S

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221086

Device Name
CryoRobot Select System

Indications for Use *(Describe)*
The CryoRobot Select System consists of the CryoRobot Select, CryoBeacons, and CryoTransporter. The indications for use for the CryoRobot Select System is shown below:

The CryoRobot Select System is intended to provide an automated liquid nitrogen storage system for oocytes, embryos, and sperm to facilitate the identification, storage, and retrieval of specimens.

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.

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510(k) Summary – K221086

I. SUBMITTER:

Manufacturer: TMRW Life Sciences, Inc.
250 Hudson Street, 6th Floor
New York, NY 10013

Phone: 1-866-733-TMRW

Email: ra@tmrw.org

Contact Person: Christina Miracle

Date Prepared: November 1, 2022

II. DEVICE

Trade Name of Device: CryoRobot Select System

Common Name: Automated Cryopreservation Storage System

Regulation Name: Assisted Reproduction Accessories

Regulation Number: 21 CFR 884.6120

Regulatory Class: Class II

Product Code: QUJ (Automated Cryopreservation Storage System)

III. PREDICATE DEVICE

Primary Predicate Device: Kryo ART Controlled Rate Freezer (K032086)

Manufacturer: PLANER, plc.

Product Code: MQG (Assisted Reproduction Accessory)

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

The Agency cleared the predicate device with the product code MQG. On July 11, 2017, Federal Register Notice 82 FR 31976 exempted controlled-rate cryopreservation freezers. A 510(k) is not needed to market a controlled-rate cryopreservation freezer if it does not exceed the limitation of

exemption found in 21 CFR 884.9. Therefore, the predicate device now falls under product code PUB (Accessory, Assisted Reproduction, Exempt).

A 510(k) submission was required for the subject device, as it exceeded the limitations of exemption per 21 CFR 884.9.

IV. DEVICE DESCRIPTION

The CryoRobot Select System includes the CryoRobot Select (the robot), CryoBeacons, and the CryoTransporter.

The CryoRobot Select System provides an automated liquid nitrogen storage system for oocytes, embryos, and sperm to facilitate the identification, storage, and retrieval of specimens. The system consists of a cryogenic tank, robotic hardware for automation, dedicated robot control software, RFID-enabled storage units ("CryoBeacons") and an insulated container for carrying multiple CryoBeacons ("CryoTransporters").

The robot has an automated container picking system, designed to pick and transport individual CryoBeacons to and from the cryogenic tank. The robot allows users to load 24 CryoBeacons at a time, with a freezer storage capacity of 1,386 through a user-accessible drawer. The system maintains cryogenic temperatures during the specimen storage and retrieval processes.

The CryoBeacon is a radio-frequency identification (RFID) enabled storage unit that holds up to eight dimensionally compatible cryodevices. TMRW does not manufacture cryodevices for use with CryoBeacons. Cryodevices compatible with the CryoBeacon include devices up to 135 mm long with the gametes or embryos located at or below 50 mm when measured from the distal end of the closed device.

The CryoTransporter is an insulated cryogenic container for carrying 24 CryoBeacons to and from the CryoRobot Select system. The CryoTransporter is filled with liquid nitrogen to maintain a cryogenic environment during CryoBeacon transport. For safe carrying, the CryoTransporter has a handle and a vented, transparent lid for viewing its contents. The CryoTransporter is placed in the drawer of the CryoRobot Select to transfer or retrieve CryoBeacons from the cryogenic tank.

V. INDICATIONS FOR USE

The CryoRobot Select System consists of the CryoRobot Select, CryoBeacons, and CryoTransporter. The indications for use for the CryoRobot Select System is shown below:

The CryoRobot Select System is intended to provide an automated liquid nitrogen storage system for oocytes, embryos, and sperm to facilitate the identification, storage, and retrieval of specimens.

VI. COMPARISON OF THE INTENDED USE AND TECHNOLOGICAL CHARACTERISTICS OF THE SUBJECT AND PREDICATE DEVICE

Parameter	Subject Device (K221086)	Predicate Device (K032086)	Comparison
Indications for Use	The CryoRobot Select System consists of the CryoRobot Select, CryoBeacons, and CryoTransporter. The indications for use for the CryoRobot Select System is shown below: The CryoRobot Select System is intended to provide an automated liquid nitrogen storage system for oocytes, embryos, and sperm to facilitate the identification, storage, and retrieval of specimens.	The Kryo ART brand of controlled rate freezers are intended to be used to freeze gametes or embryos at a user determined rate.	The indications for use of the subject device is not identical to that of the predicate device. However, the two devices have the same intended use, which is to contain, freeze, and maintain gametes and/or embryos at an appropriate freezing temperature.
Software	Software-controlled	Software-controlled	Same
Design	The CryoRobot Select System includes an insulated CryoTransporter to transport CryoBeacons holding cryodevices containing gametes and embryos to the loading/retrieval drawer of the CryoRobot Select. The CryoRobot Select identifies the presence or absence of CryoBeacons in the drawer and uses this information to determine whether a storage or retrieval procedure will occur. The CryoRobot Select will then transport the CryoBeacons to or from the storage tank one at a time. The	Controlled rate liquid nitrogen freezers with different chamber sizes to cryopreserve samples.	Different

	CryoRobot Select maintains the samples at cryogenic temperatures by maintaining exposure to liquid nitrogen throughout sample transport.		
Gamete/Embryo-Contacting	No. Samples in cryodevices are loaded in device.	No. Samples in cryodevices are loaded in device.	Same
Tank Size	250 L storage tank	Dewar sizes: 1.7 L 3.3 L 16 L	Different
Number of Samples	1,386 CryoBeacons	Not known	Different
User Interface	Touchscreen and specimen management software	MRV controller system	Different
Components	CryoRobot Select CryoBeacons CryoTransporter	Not known	Different
RFID	Yes	No	Different

As shown in the table, the subject and predicate device do not have identical indications for use statements; however, they have the same intended use (i.e., to contain, freeze, and maintain gametes and/or embryos at an appropriate freezing temperature).

There are similarities in the technologies between the subject and proposed predicate device, including the following:

- Both are software-controlled devices.
- Both monitor temperature and use liquid nitrogen to freeze and/or maintain samples at cryogenic temperatures for purposes of long-term storage.
- Both include features to provide liquid nitrogen from storage tanks to cool and maintain the cryogenic state of samples.
- Both devices are able to provide information on their status/performance to device users.

Differences in technology include the following:

- The subject device includes RFID features to identify the presence of CryoBeacons in the drawer of the CryoRobot Select that inform the system to prepare for an automated loading or retrieval procedure initiated by the user. This represents automation of the manual process done for samples after freezing using the predicate device. Although the predicate does not include these features, they do not raise different questions of S&E as compared to the proposed predicate (i.e., both devices raise similar S&E questions: will samples remain frozen during device use?, will a failure lead to sample damage or loss?, will a sample be mis-identified?, etc.).

- The subject device CryoTank design is for long-term storage as opposed to the design of the proposed predicate that is for holding samples for a short duration after freezing. This difference does not raise different questions of safety and effectiveness, as both devices are intended to maintain samples in a cryogenic state while within the device (similar questions to that stated above).
- The subject device transfers a maximum of 24 CryoBeacons to or from the storage tank during a loading or retrieval operation and can hold a maximum of 1,386 CryoBeacons in the 250 L storage tank. The maximum number of samples the predicate device equipped with dewar sizes of 1.7-16 L can freeze and maintain in a single run is not known. Differences in the number of samples that can be processed in a single use of the device or the total number of samples that can be maintained in the device do not raise different questions of S&E between the two devices (i.e., both devices raise similar S&E questions: can the devices maintain the cryogenic state of the maximum number of samples loaded in device?).
- The subject and predicate devices have different user interface systems that are used to operate and receive information on device function status. Differences in user interface systems do not raise different questions of safety and effectiveness.

VII. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING

Reprocessing

Reprocessing instructions were based on validated cleaning and disinfection testing conducted in accordance with the 2015 FDA guidance document "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling."

Electrical Safety and Electromagnetic Compatibility

Testing was conducted in accordance with:

- IEC 60601-1-2:2014, Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests
- IEC 61010-1 Edition 3.1 2017-01 Consolidated version, Standard for Safety for Electrical Equipment for Measurement, Control and Laboratory Use, Part 1: General Requirements

Wireless Technology

The wireless technology features of the device were assessed in accordance with the 2007 FDA guidance "Radio Frequency Wireless Technology in Medical Devices - Guidance for Industry and Food and Drug Administration Staff."

Software

Software was evaluated in accordance with the 2005 FDA guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

Cybersecurity

Cybersecurity was evaluated in accordance with the 2014 FDA guidance document "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices."

Performance Testing

Performance testing was conducted to demonstrate the system performs as expected in the following areas:

- Auto position testing to demonstrate capability of the robot to pick and place samples to and from the CryoTransporter and CryoRobot Select storage tank.
- Manual drawer opening/closing to confirm that the drawer can be opened and closed manually.
- Thermal performance tests to monitor the temperature of cryodevices during loading, storage, and retrieval to ensure the sample is not compromised and to ensure delivery of liquid nitrogen when necessary.
- RFID traceability verification tests to ensure the reliability of the RFID features.
- System safety verification testing to ensure that all safety systems operate as intended (e.g., alarms, emergency liquid nitrogen system activation, uninterruptable power supply function, drawer position, drawer finger trap testing, etc.).
- Freezer hold time assessment to verify the hold time window in which specimens remain below the acceptable temperature without power and liquid nitrogen supply.
- CryoTank verification tests to ensure the tank maintains samples during storage.

VIII. CONCLUSIONS

The results of the testing described above demonstrate that the subject device is as safe and effective as the predicate device and support a determination of substantial equivalence.