March 8, 2018

DxNow, Inc.
Kevin Sly
Senior Advisor to DxNow, Inc.
401 Professional Drive, Suite 130
Gaithersburg, Maryland 20879-3429

Re: K173075
Trade/Device Name: ZyMot ICSI Sperm Separation Device,
ZyMot Multi Sperm Separation Device (850µl, 3ml)
Regulation Number: 21 CFR 884.6160
Regulation Name: Assisted Reproduction Labware
Regulatory Class: Class II
Product Code: MQK
Dated: February 6, 2018
Received: February 6, 2018

Dear Kevin Sly:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Benjamin R. Fisher -S

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173075

Device Name
ZyMōt ICSI Sperm Separation Device
ZyMōt Multi Sperm Separation Device (850µl, 3ml)

Indications for Use *(Describe)*

The ZyMōt ICSI Sperm Separation Device is intended for preparing motile sperm from semen for use in the treatment of infertile couples by intracytoplasmic sperm injection (ICSI) procedures.

The ZyMōt Multi Sperm Separation Device is intended for preparing motile sperm from semen for use in the treatment of infertile couples by intracytoplasmic sperm injection (ICSI), in vitro fertilization (IVF) and intrauterine insemination (IUI) 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
K173075

1. Submitter

DxNow, Inc.
401 Professional Drive, Suite 130
Gaithersburg, MD 20879-3429
Contact: Bill Sharp, CEO
Email: bsharp@dxnowinc.com
Phone: 240-454-9893

2. Correspondent

Kevin Sly
Senior Advisor, DxNow, Inc.
Email: ksly@dxnowinc.com
Phone: 240-751-6521

3. Date Prepared: March 6, 2018

4. Device Identification:

Trade name:	ZyMōt ICSI Sperm Separation Device ZyMōt Multi Sperm Separation Device (850µl, 3ml)
Common name:	Sperm Separation Device
Classification name:	Assisted Reproduction Labware (21 CFR 884.6160)
Product code:	MQK (Labware, Assisted Reproduction)
Regulatory class:	II

5. Predicate Device

Qualis (K133295). This predicate device has not been subject to any design related recalls.

6. Device Description

The ZyMōt ICSI Sperm Separation Device and ZyMōt Multi Sperm Separation Device (850µl, 3ml) are used to prepare motile sperm for assisted reproductive technology (ART) procedures. They separate motile sperm from the semen based on the mobility (i.e., swim-up nature) of motile sperm.

The ZyMōt ICSI Sperm Separation Device has five micro-channels, each accommodating 2µl of semen and processes up to five separations from one semen sample. Each channel has an inlet port for applying the semen sample and an outlet port for collecting the motile sperm. The ports are connected by a fluid-filled micro-channel in which separation occurs.

The ZyMōt Multi Sperm Separation Device has two processing volumes, 850µl and 3ml. Each version has an inlet port that communicates with the lower sample chamber. The sample chamber is separated from the upper collection chamber by a microporous filter. Untreated semen is added through the inlet port. After incubation, the separated motile sperm are collected from the upper chamber through the outlet port.

The subject devices are radiation-sterilized devices with a sterility assurance level (SAL) of 10^{-6}. They are individually packaged and for single-use only.

7. Indications for Use

The ZyMōt ICSI Sperm Separation Device is intended for preparing motile sperm from semen for use in the treatment of infertile couples by intracytoplasmic sperm injection (ICSI) procedures.

The ZyMōt Multi Sperm Separation Device is intended for preparing motile sperm from semen for use in the treatment of infertile couples by intracytoplasmic sperm injection (ICSI), in vitro fertilization (IVF) and intrauterine insemination (IUI) procedures.

8. Comparison of Intended Use and Technological Characteristics with the Predicate Device

Device/Predicate Device(s):	K173075 (subject devices)	K133295 (predicate device)
Indications for Use	The ZyMōt ICSI is intended for preparing motile sperm from semen for use in the treatment of infertile couples by intracytoplasmic sperm injection (ICSI) procedures. The ZyMōt Multi is intended for preparing motile sperm from semen for use in the treatment of infertile couples by intracytoplasmic sperm injection (ICSI), in vitro fertilization (IVF) and intrauterine insemination (IUI) procedures.	The Qualis is intended for preparing motile human sperm for use in the treatment of infertile couples by intracytoplasmic sperm insertion (ICSI) fertilization.
Design	ZyMōt ICSI – A disposable culture dish containing five micro-channels, each connected to an inlet port and an outlet port ZyMōt Multi – A disposable culture dish containing a separation chamber and an inlet port. The separation chamber has a lower sample chamber and an upper	A disposable culture dish with four chambers connected by micro-channels

	collection chamber. The two chambers are separated by a microporous filter.	
Mechanism of action	ZyMōt ICSI – The inlet port is preloaded with sperm separation medium and then loaded with semen. After incubation at 37°C for 30 min, the motile sperm are collected from the outlet port. ZyMōt Multi – The semen is added to the inlet port to fill the lower sample chamber; then, the separation medium is added to the upper collection chamber. The loaded device is incubated at 37°C for 30 min to allow motile sperm to swim up and cross the filter to migrate into the over-laying separation medium in the upper collection chamber.	The semen sample is placed in Chamber A and separation medium is placed in Chamber B. Fluids from both chambers flow via the micro-channels into the central micro-channel where the two fluids pass side-by-side in laminar flow. Motile sperm can swim across the interface of the laminar flow streams and pass into the separation medium stream but non-motile sperm and debris cannot. Motile sperm that cross into the separation medium flow are carried into Chamber C where they are collected. Non-motile sperm and debris remain in the semen sample flow from Chamber A into Chamber D.
Material	ZyMōt ICSI – Polymethylmethacrylate, borosilicate glass, flash-spun high-density polyethylene fibers ZyMōt Multi – Polymethylmethacrylate, polycarbonate, flash-spun high-density polyethylene fibers	Cyclo-olefin polymer

The subject and predicate devices have different Indications for Use statements; however, they have the same intended use – preparing motile sperm from semen for use in ART procedures.

The subject and predicate devices have the same fundamental design incorporating a culture dish with an inlet port/chamber for loading of semen and an outlet port/chamber for collection of motile sperm. Both devices rely on sperm motility to separate motile sperm from non-motile sperm or non-sperm cells. The predicate device incorporates microfluidic technology, whereas the subject devices do not. However, this difference does not raise different questions of safety and effectiveness as compared to the predicate device, as both devices (and other cleared devices) have the same fundamental mode of action (i.e., using motility of sperm to prepare pools of motile sperm for use in ART procedures). In addition, the subject and predicate devices have different materials. However, differences in materials do not raise different questions of safety and effectiveness as compared to the predicate device.

9. Summary of Non-Clinical Performance Testing:

The following studies have been performed to support substantial equivalence to the predicate devices:

- Sterilization validation study per ISO 11137-2:2012
- Transportation simulation study per ASTM D5276-98
- Package integrity testing following accelerated aging per ASTM F1980-07 to support a 12-month shelf-life:
    - Dye penetration testing per ASTM F1929-98
    - Seal strength testing per ASTM F88/F88M-15
- Endotoxin testing per USP<85>: ≤2.15 EU/device
- Human sperm survival assay (HSSA) before and after accelerated aging to support a 12-month shelf-life:

  Donor sperm were exposed to the subject devices for 30 minutes and then, incubated at room temperature for 24 hours. The rate of motile sperm after incubation was compared to that of the control (no exposure to the subject device). The acceptance criterion is ≥80% of the control motility at 24 hours after exposure for 30 minutes.
- Performance testing:

  Each version of the subject device was used to separate motile sperm from donor semen samples. The separation procedures followed the Instructions for Use, and the percentage of motile sperm and progressively motile sperm in the output samples were compared to those of the input samples. A summary of the results is provided in the table below:

Device	Percentage of motile sperm (before/after separation)	Percentage of progressively motile sperm (before/after separation)
ZyMōt ICSI	29.7% / 87%	26.3% / 74.2%
ZyMōt Multi 850µl	67% / 83.6%	44.7% / 68.6%
ZyMōt Multi 3ml	67% / 86.5%	44.7% / 75.4%

10. Conclusion

The subject and predicate devices 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 devices are substantially equivalent to the predicate device.