April 24, 2024

FUJIFILM Irvine Scientific
Cindy Kha
Regulatory Affairs Specialist II
2511 Daimler Street
Santa Ana, California 92705

Re: K233764
Trade/Device Name: SSS-NX (Serum Substitute Supplement-NX)
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive Media And Supplements
Regulatory Class: II
Product Code: MQL
Dated: November 22, 2023
Received: November 24, 2023

Dear Cindy Kha:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

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)*
K233764

Device Name
SSS-NX (Serum Substitute Supplement-NX)

Indications for Use *(Describe)*
SSS-NX is intended for use in assisted reproductive technology (ART) procedures which include gamete and embryo manipulation and culture. These procedures include the use of SSS-NX as a supplement for ART media.

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."

510(k) SUMMARY
K233764

Submitter/Address	FUJIFILM Irvine Scientific, Inc. 2511 Daimler Street Santa Ana, CA 92705 Telephone: 949 261-7800
Contact Person:	Cindy Kha FUJIFILM Irvine Scientific, Inc. 2511 Daimler Street Santa Ana, CA 92705 Telephone: 949 261-7800 Email: cindy.kha@fujifilm.com
Date Prepared:	April 24, 2024
Trade Name:	SSS-NX (Serum Substitute Supplement-NX)
Common Name:	Assisted reproduction media supplement
Regulation Name:	Reproductive media and supplements
Regulation Number:	21 CFR 884.6180
Regulatory Class:	Class II
Product Code:	MQL (Media, Reproductive)
Predicate Device:	Serum Substitute Supplement (SSS) 510(k): K983579 Irvine Scientific Sales Co., Inc. The predicate device has not been subject to a design-related recall

Device Description

SSS-NX (Serum Substitute Supplement-NX) is an assisted reproduction media supplement consisting of a combination of human serum proteins (approximate protein content 50 mg/mL, 5% w/v) in a saline solution. Of this, ≥83% is albumin and ≤17% is globulins. The product is supplied as a ready to use liquid in 10 mL containers distributed in a twelve (12) x 10 mL kit and a 100 mL liquid packaged in a 125 mL container.

Indications for Use

SSS-NX is intended for use in assisted reproductive technology (ART) procedures which include gamete and embryo manipulation and culture. These procedures include the use of SSS-NX as a supplement for ART media.

Comparison of Intended Use and Technological Characteristics of the Subject and Predicate Devices

A comparison of the intended use and technological characteristics of the subject device and the predicate device is shown in the table below:

	Subject Device SSS-NX (Serum Substitute Supplement-NX)	Predicate Device K983579 Serum Substitute Supplement (SSS)	Comparison
Indications for Use	SSS-NX is intended for use in assisted reproductive technology (ART) procedures which include gamete and embryo manipulation and culture. These procedures include the use of SSS-NX as a supplement for ART media.	Serum substitute supplement (SSS) is designed for those assisted reproductive procedures that require the use of a protein supplement. In particular, SSS is intended for use during in vitro fertilization, during in vitro embryo culture to the desired stage of embryo development, and for the cryopreservation of human embryos.	**Different** – There are differences in the subject and predicate device indications for use statements; however, both have the same intended use (i.e., for manipulation of gametes and embryos and for culture use).
Intended Use	SSS-NX is intended for use in assisted reproductive technology (ART) procedures which include gamete and embryo manipulation and	SSS is intended for use in assisted reproductive procedures which include gamete and embryo manipulation. These procedures include the use of SSS as a	**Same** – The subject and predicate devices include gamete and embryo manipulation and for culture use.

	culture. These procedures include the use of SSS-NX as a supplement for ART media.	supplement for culture medium.	
Conditions of Use	Rx Only	Rx Only	**Same**
Device Materials	Plasma Protein Fraction	Plasma Protein Fraction (mixture of separate components on-site) • Human Serum Albumin (20% for use in manufacturing reproductive products) • α-Globulin, Human, Fraction IV (5% solution)	**Different** – The formulas of the subject and predicate devices are not the same. Differences in media formulations do not raise different questions of safety and effectiveness (S&E).
Aseptically Filtered	Yes	Yes	**Same**
Sterility	Sterile (No Growth) USP <71>	Sterile (No Growth) USP <71>	**Same**
pH	7.2 – 7.6	7.2 – 7.6	**Same**
Osmolality (mOSM/kg)	272 – 288	272 – 288	**Same**
Endotoxin (EU/ml)	≤ 0.5	≤ 3.0	**Different** – The subject device has a more stringent endotoxin limit. Differences in endotoxin limit do not raise different questions of safety and effectiveness (S&E).
Mouse Embryo Assay (MEA)	1-cell: ≥ 80% embryos developed to expanded blastocyst at 96 hours	1-cell: ≥ 80% embryos developed to expanded blastocyst at 96 hours	**Same**
Shelf Life	8 months	2 years	**Different** – The subject device has a shorter shelf life.

As shown in the table above, there are differences in the Indications for Use statements and technological features of the subject and predicate devices. However, the subject and predicate device have the same Intended Use and the differences in technological features do not raise different questions of safety and effectiveness.

Non-Clinical Performance Data

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

- Sterile filtration and aseptic fill validation, per ISO 13408-1:2008 – Aseptic Processing of Health Care Products – Part 1 General Requirements (including Amendment 1 (2013)) and ISO 13408- 2:2018 – Aseptic Processing of Health Care Products – Part 2 Sterilizing Filtration.

- Shelf-life testing was conducted to support the 8-month shelf-life for the subject device through demonstration that the product specifications (shown below) were met at time 0 and after accelerated aging in accordance with ASTM F1980-21. Testing conducted is shown below:
    - Clarity/Color: Amber, Clear, Free of particulate matter
    - pH, per USP<791>: 7.2 – 7.6
    - Osmolality, per USP<785>: 272 – 288 mOsm/kg
    - Endotoxin, per USP <85>: < 0.5 EU/mL
    - MEA: 1-Cell System: ≥80% of embryos developed to expanded blastocyst at 96h
    - Sterility, per USP<71>: No growth

- Transportation testing per ASTM D4169-22

Conclusions

The results of the testing described above provide demonstrate that the SSS-NX (Serum Substitute Supplement-NX) is as safe and effective as the predicate device and supports and determination of substantial equivalence.