July 12, 2024

DuoGenic StemCells Corporation
Hong-Lin Su
Chairman
No. 18, Ln. 10, Taiping 21st St., Taiping Dist.
Taichung City, Taiwan 41161
Taiwan

Re: K240247
Trade/Device Name: "MoFi" Cell Culture Basal Medium
Regulation Number: 21 CFR 876.5885
Regulation Name: Tissue Culture Media For Human Ex Vivo Tissue And Cell Culture Processing Applications
Regulatory Class: Class II
Product Code: NDS
Dated: June 14, 2024
Received: June 14, 2024

Dear Hong-Lin Su:

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,

Maura Rooney -S

Maura Rooney
Assistant Director
DHT3A: Division of Renal,
Gastrointestinal, Obesity
and Transplant 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240247

Device Name

"MoFi" Cell Culture Basal Medium

Indications for Use *(Describe)*

MoFi is a liquid culture medium intended for human ex vivo tissue and cell culture processing applications.

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."

Ch. 5 – 510(k) Summary

Date: 03/07/2024

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CRF 872, this information serves as a Summary of Safety and Effectiveness for the use of the "MoFi" Cell Culture Basal Medium (hereinafter referred to as MoFi).

Submitted by	DuoGenic StemCells corporation
Date	2024/07/03
Contact Person	Chih-Yao Lin
Applicant Address	No. 18, Ln. 10, Taiping 21st St., Taiping Dist., Taichung City, Taiwan (R.O.C.)
Telephone Number	+886-4-2276-6193
Proprietary Name	"MoFi" Cell Culture Basal Medium
Common Name	MoFi
Device Trade Name	MoFi
Review Panel	Gastroenterology/Urology
Classification Name and Reference	876.5885 Tissue culture media for human ex vivo tissue and cell culture processing applications. Class II (special controls).
Device Product Code and Panel Code	NDS
Predicate Device	KnockoutTM SR Medium and KnockoutTM SR Xenofree Medium
Predicate Submission Number	K100616

1. Intended Use and Indications for Use

MoFi is a liquid culture medium intended for human *ex vivo* tissue and cell culture processing applications.

2. Device Description

2.1 **Description:**

MoFi is a basal medium based on Iscove's Modified Dulbecco's Medium (IMDM) and cell-degradable polysaccharide, made of water, carbohydrate, amino acid and salt. It can be mixed with various serums or additional additives to form a complete medium, which can be used to culture suspension/adherent primary cultured cells or cell lines. MoFi provides cells with energy to maintain survival and promote growth.

2.2 **Storage condition:** 2 - 6°C

2.3 **Shelf life:** 9 months (from the manufactured date)

2.4 **Volume:** 80 mL/bottle

2.5 **Instruction:**

2.5.1 The preparation of full medium is recommended according to the cell type. Please see the table below. Antibiotics may be added if needed.

2.5.2 Temperature and time for pre-warming can be adjusted according to user's need, while it's recommended not to exceed 37°C.

2.5.3 This product is recommended to be handled aseptically.

Concentration / Reagent	Peripheral Blood Cells (suspension cells)	Mesenchymal Stem Cells (adherent cells)
MoFi	1X	1X
Serum (human or animal)	10%	20%
L-glutamine	2 mM	2 mM
Sodium pyruvate	1 mM	1 mM
Non-essential amino acids	Not applicable (N/A)	0.1 mM
Fibroblast growth factor 2	N/A	4 ng/mL

2.6 **Warning and Precautions:**

2.6.1. Protective glasses, clothing and gloves should be worn during operation.

2.6.2. This product is for single use, and should not be re-sterilized and reused.

2.6.3. This product should be handled aseptically, and should follow biosafety instructions.

2.6.4. This product should be protected from light.

2.6.5. This product should not be stored or operated at over 37°C.

2.6.6. Please do NOT inject this product into the human body, or allergic reactions may occur.

2.6.7. When used as a medical device, Federal Law restricts this device to sale by or on the order of a physician.

3. Device Specification

3.1 **Appearance:** Transparent yellowish liquid

3.2 **pH:** 7.0-8.0

3.3 **Cell viability**

3.4 **Sterility:** Negative or not detected

3.5 **Endotoxin**: < 1 EU/mL

3.6 **Mycoplasma**: Negative or not detected

4. Substantial Equivalence Information

Predicate Device: Knockout™ SR Medium and Knockout™ SR Xenofree Medium

Manufacturer: Life Technologies Corporation

Item	New device (applicant)	Predicate device
Regulation number & product code	876.5885 NDS	876.5885 NDS
510(k) Number	K240247	K100616
Intended Use	A liquid culture medium intended for human *ex vivo* tissue and cell culture processing applications	A liquid tissue culture media product intended for human *ex vivo* tissue and cell culture processing applications
Comparison: Both MoFi and the predicate are used for human *ex vivo* cell and tissue processing applications.		
Container/ packaging	Bottle: polyethylene terephthalate copolyester, glycol modified $(PETG)_2/O_2$ Closure: high-density polyethylene (HDPE)	Bottle: polyethylene terephthalate (PET) Closure: high-density polyethylene (HDPE)
Comparison: PET and PETG are both suitable containers for cell culture and media storage applications.		
Product Configuration	Amino acids, salts, vitamins and carbohydrates	Amino acids, salts, vitamins and carbohydrates
Comparison: Both MoFi and the predicate are chemically-defined culture media and composed of amino acids, salts, vitamins and carbohydrates.		
Aseptically Processed	Compliance with GMP requirements regarding aseptic processing	Compliance with GMP requirements regarding aseptic processing
Comparison: The process validation and environmental monitoring of the MoFi process support aseptic processing. Both MoFi and the predicate comply with GMP requirements regarding aseptic processing.		
Storage Temperature	2-6°C	2-8°C
Comparison: The difference in storage temperature between MoFi and the predicate does not affect the safety of the product.		
Shelf-life	9 months	14 months
Comparison: According to the stability data, shelf life of MoFi is recommended to be 9 months.		
Product Performance	Good cell viability and normal cell morphology of four kinds of cells (suspension primary culture cells, suspension cell lines, adherent primary culture cells and adherent cell lines)	Good cell viability and normal cell morphology of four kinds of cells (suspension primary culture cells, suspension cell lines, adherent primary culture cells and adherent cell lines)
Comparison: Cells are roughly categorized into four groups, suspension primary culture cells, suspension cell lines, adherent primary culture cells and adherent cell lines. The results showed that both KSR and MoFi passed the acceptance criteria of cell viability, and the cell morphology of four kinds of cells cultured in both MoFi and the predicate is normal and typical. This indicates that MoFi possess an equivalent function as the predicate, and no safety issues occur.		

5. Shelf Life

According to the stability test's result, shelf life for MoFi is recommended to be 9 months.

6. Biocompatibility

The biocompatibility evaluation was conducted in accordance with the FDA Guidance "Use of International Standard ISO 10993-1,"Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.

7. Performance Testing

All batches tested met the acceptance criteria of performance testing. The residual endotoxin is well controlled. No bacteria and mycoplasma were detected. The residues of plasticizers, heavy metals and particles are not detected or can be safely ignored.

8. Conclusion

MoFi and Knockout™ SR Medium and Knockout™ SR Xenofree Medium are used for human *ex vivo* tissue and cell culture processing applications and have the same/similar container, storage temperature, efficacy (generic cellular growth and maintenance) and safety (consistency in chemical content and formulation, biocompatibility with cells, and purity). Their efficacy in supporting the survival, growth, development, and maintenance of human cells or tissue culture systems has been well established in scientific publications included in this submission. These products (MoFi and Knockout™ SR Medium and Knockout™ SR Xenofiree Medium) are manufactured in accordance with QSR requirements and are labeled as aseptically processed. Thus, MoFi are substantially equivalent to the legally marketed device (K100616) intended for the human *ex vivo* tissue and cell culture processing applications.