September 6, 2024

Yocon Biology Technology Company
Haifeng Li
QA Manager
3/F, Bldg. B, No.7, Fengxian Rd. YongFeng Base
Haidian District
Beijing, Beijing 100094
China

Re: K232543
Trade/Device Name: MSC SFM
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: August 5, 2024
Received: August 7, 2024

Dear Haifeng Li:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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.*

510(k) Number *(if known)*
K232543

Device Name
MSC SFM

Indications for Use *(Describe)*
MSC SFM is a liquid tissue culture medium product 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:

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*"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

Prepared in accordance with the requirements of 21 CFR Part 807.92

## 1. Submitter's Information

Name: YOCON BIOLOGY TECHNOLOGY COMPANY
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Contact Person: Haifeng Li
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Tel: +86-10-58711655

**2. Date Prepared:** December 6th, 2023

## 3. Device Information:

Trade/Device Name: MSC SFM
Device Common Name: MSC SFM
Regulation Number: 21 CFR 876.5885
Regulation Name: Tissue Culture Media For Human Ex Vivo Tissue And Cell Culture Processing Applications
Regulation Class: II
Product Code: NDS

## Predicate Device (K103302)

Trade/Device Name: StemPro MSC SFM Medium
Device Common Name: StemPro MSC SFM
Manufacturer Life Technologies Corporation

Regulation Number: 21 CFR 876.5885
Regulation Name: Tissue Culture Media For Human Ex Vivo Tissue And Cell Culture Processing Applications
Regulation Class: II
Product Code: NDS

## 4. Device Description

MSC SFM is a serum-free medium specially formulated for the growth and expansion of human mesenchymal stem cells (MSCs). MSC SFM contains MSC SFM Basal Medium and MSC SFM supplement, MSC SFM supplement is a growth factor that should be added to the MSC SFM Basal Medium when use. Using MSC SFM, human MSCs can be expanded for multiple passages while maintaining their trilineage mesoderm potential (i.e., ability to differentiate into osteogenic, chondrogenic and adipogenic lineages). Each container is aseptically filled.

## 5. Indication for use

MSC SFM is a liquid tissue culture medium product intended for human ex-vivo tissue and cell culture processing applications.

## 6. Comparison to Predicate Device

Comparison to the predicate devices, the subject device has same intended use, similar product design, same performance effectiveness, performance safety as the predicate device as summarized in the following table.

| **Feature** | **Subject device** | **Predicate device**<br>**K103302** | **Comments** |
|---|---|---|---|
| Manufacturer | YOCON BIOLOGY TECHNOLOGY COMPANY | Life Technologies Corporation | -- |
| Trade name | MSC SFM | StemPro MSC SFM Medium | -- |
| Classification's name and Regulation Name | Regulation Number: 21 CFR 876.5885<br>Regulation Name: Media, Culture, Ex Vivo, Tissue And Cell<br>Regulation Class: Class II<br>Product Code: NDS | Regulation Number: 21 CFR 876.5885<br>Regulation Name: Media, Culture, Ex Vivo, Tissue And Cell<br>Regulation Class: Class II<br>Product Code: NDS | Same |
| Indications for use | MSC SFM is a liquid tissue culture medium products intended for human ex-vivo tissue and cell culture processing applications. | StemPro MSC SFM Medium is a liquid tissue culture medium products intended for human ex-vivo tissue and cell culture processing applications. | Same |
| Ingredients | Glycine, L-Alanine, L-Arginine HCl, Asparagine monohydrate, L-Aspartic acid, L-Cysteine HCl H2O, L-Glutamic Acid, L-Glutamine, L-Histidine HCl H2O, L-Isoleucine, L-Leucine, L-Lysine HCl, L-Methionine, L-Phenylalanine, L-Proline, L-Serine, L-Threonine, L-Tryptophan, Tyrosine, L-Valine, Choline chloride, D-Calcium pantothenate, Folic Acid, Niacinamide, Pyridoxal HCl, Riboflavin, Thiamine | Confidential | Different,<br>The formulation of the predicate device is not available because the formulation is confidential. |

| | | | |
|---|---|---|---|
| | HCl, Vitamin B12, i –Inositol, Calcium Chloride (CaCl2)<br>Anhydrous, Magnesium Chloride<br>(MgCl2 anhydrous), MagnesiumSulfate<br>(MgSO4)-7H2O, Potassium Chloride (KCl), Sodium Bicarbonate<br>(NaHCO3), Sodium Chloride (NaCl), Sodium Phosphate dibasic<br>(Na2HPO4)-7H2O, Sodium Dihydrogen<br>Phosphate-1H2O, D-Glucose (Dextrose), Hypoxanthine Na, Sodium Pyruvate, Biotin, Cupric sulfate, Iron(III)nitrate nonahydrate (Fe[NO3]3·9[H2O]), Ferrous Sulfate(FeSO4-7H2O), Linoleic Acid, Lipoic Acid, Putrescine2HCl, Sodium Selenite(Na2SeO3), Recombinant Human Transferrin, Recombinant Human serum albumin, Recombinant Human Insulin, Recombinant Human Fibronectin, EGF | | |
| Demonstrate lack of potential toxicity of materials in the media to cells or tissue and demonstrate support of tissue and cell growth | Performance Assay | StemPro MSC SFM<br>Performance Assay | Different,<br>The performance assay data of predicate device is not available because this information is confidential. We have conducted non-clinical testing. Results of the testing demonstrate a lack of potential toxicity of the materials in the media to cells or tissue and demonstrates support of tissue and cell growth. |

| | | | |
|---|---|---|---|
| Endotoxin and Pyrogen contamination | Bacterial Endotoxin<0.25EU/mL(USP <85>) | Limulus Ameobocyte (LAL) test (25 USP Monograph <85>) | Same |
| Validation of Aseptic Processing and Sterility Assurance Level (SAL) | Through the validation of Aseptic processing and Sterility Assurance Level (SAL), determine that SAL l0-3 compliance with GMP requirements regarding aseptic processing. | Through the validation of Aseptic processing and Sterility Assurance Level (SAL), determine that SAL l0-3 compliance with GMP requirements regarding aseptic processing | Same |

## 7. Performance Data

**Clinical test:**

Clinical testing is not required.

**Non-clinical data**

Performance:

Performance standards under Section 514 of the Federal Food, Drug, and Cosmetic Act have been established in Guidance Document "Class II Special Controls Guidance Document: Tissue Culture Media for Human Ex Vivo Tissue and Cell Culture Processing Applications; Final Guidance for Industry and FDA Reviewers," issued May 16, 2001. The specific assay tests and Yocon Biology's equivalent tests are described below.

- Validation of aseptic processing compliance with GMP requirements regarding aseptic processing
- Sterility Assurance Level (SAL) $\geq 10^{-3}$
- Appearance and clarity
- Osmolality Testing
- pH value Testing
- Sterility Testing
- Endotoxin Testing
- Performance Assay

Shelf Life:

YOCON BIOLOGY TECHNOLOGY COMPANY performs shelf-life testing for subject device using retained product stored at 2-8℃, and subject device is performed performance testing over 12 months. The test results support a shelf life of 12 months for MSC SFM.

Biocompatibility:

The Biological Evaluation compliance with the standards of ISO 10993-1, “Biological Evaluation of Medical Devices”.

## 8. Conclusion

Yocon MSC SFM is substantially equivalent to StemPRO®MSC SFM Medium 510(k) K103302.