April 19, 2024

FetTech
Clay Fette, CEO
10871 NW 52nd St, Ste 4
Sunrise, Florida 33351

Re: K232204
Trade/Device Name: ReyaGel (RG03 - MTP gel 3mL)
Regulatory Class: Unclassified
Product Code: KGN
Dated: March 18, 2024
Received: March 19, 2024

Dear Clay Fette:

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,

Mustafa A. Mazher -S

for Yu-Chieh Chiu, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic and Reconstructive Surgery Devices
OHT4: Office of Surgical
and Infection Control 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.

Submission Number *(if known)*

K232204

Device Name

ReyaGel (RG03 - MTP gel 3mL)

Indications for Use *(Describe)*

ReyaGel is intended for the management of wounds that include:
• Partial and full thickness wounds
• Pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers
• Second degree burns
• Surgical wounds – donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence
• Trauma wounds – abrasions, lacerations, and skin tears
• Tunneled/undermined wounds
• Draining wounds

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) #: K232204

510(k) Summary

Prepared on: 2024-04-19

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	FetTech
Applicant Address	10871 NW 52nd St Ste 4 Sunrise FL 33351 United States
Applicant Contact Telephone	561-324-9507
Applicant Contact	Mr. Clay Fette
Applicant Contact Email	cfette@fettech.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	ReyaGel (RG03 - MTP gel 3mL)
Common Name	Wound dressing
Classification Name	Wound dressing with animal derived material
Regulation Number	Unclassified
Product Code	KGN

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K172593	XCelliStem Wound Powder	KGN

Device Description Summary

21 CFR 807.92(a)(4)

ReyaGel Wound Gel is an extracellular matrix wound product composed of porcine spleen and lung extracellular matrix in a saline gel, for the management of wounds. It is an off-white gel supplied in a syringe for topical application. The product is provided sterile for single use.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

ReyaGel is intended for the management of wounds that include:
- Partial and full thickness wounds
- Pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers
- Second degree burns
- Surgical wounds – donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence
- Trauma wounds – abrasions, lacerations, and skin tears
- Tunneled/undermined wounds
- Draining wounds

Indications for Use Comparison

21 CFR 807.92(a)(5)

The subject device and predicate device (K172593) have the same indications for use.

Technological Comparison 21 CFR 807.92(a)(6)

The subject device (ReyaGel) and predicate device (XCelliStem Wound Powder) are composed of identical animal source material composed of extracellular matrix material from porcine spleen and lung. The ReyaGel subject device has been solubilized and also contains saline. The material is sourced, harvested, and processed using identical methods. For ReyaGel, the final predicate device material is then made into a gel form to facilitate application.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Because the subject device is composed of the identical source animal material as the predicate device, the bench, animal, and clinical testing from K172593 was leveraged for the subject device. To support the substantial equivalence to the predicate due to the difference in technology, additional testing was conducted on the subject device including: protein characterization, biocompatibility including cytotoxicity, sensitization, intracutaneous irritation, acute systemic toxicity, materials mediated pyrogenicity, genotoxicity, a swine full-thickness wound healing study, and clinical testing including Human Repeat Insult Patch Testing and Skin Prick Testing.

Based on the results of the bench, animal, and clinical testing completed on the subject device, the subject device demonstrates substantial equivalence to the predicate.