October 5, 2023

PromaMedical Inc.
℅ Michael Nilo
President & Principal Consultant
Nilo Medical Consulting Group, LLC
3491 Denny Street
Pittsburgh, Pennsylvania 15201

Re: K230070

Trade/Device Name: MESORAM® Hypodermic Needle (710301); MESORAM® Hypodermic Needle (710302); MESORAM® Hypodermic Needle (712305); MESORAM® Hypodermic Needle (712315); MESORAM® Hypodermic Needle (710303); MESORAM® Hypodermic Needle (710307); MESORAM® Hypodermic Needle (710306); MESORAM® Hypodermic Needle (712308); MESORAM® Hypodermic Needle (712318); MESORAM® Hypodermic Needle (712303); MESORAM® Hypodermic Needle (712307); MESORAM® Hypodermic Needle (712306); MESORAM® Hypodermic Needle (812400); MESORAM® Hypodermic Needle (812402)

Regulation Number: 21 CFR 880.5570

Regulation Name: Hypodermic Single Lumen Needle

Regulatory Class: Class II

Product Code: FMI

Dated: November 22, 2022

Received: January 10, 2023

Dear Michael Nilo:

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,

Juliane C. Lessard -S

Juliane C. Lessard, Ph.D.
Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of Gastrorenal, ObGyn,
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Office of Product Evaluation and Quality
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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)*

K230070

Device Name

MESORAM® Hypodermic Needle (710301);
MESORAM® Hypodermic Needle (710302);
MESORAM® Hypodermic Needle (712305);
MESORAM® Hypodermic Needle (712315);
MESORAM® Hypodermic Needle (710303);
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MESORAM® Hypodermic Needle (712306);
MESORAM® Hypodermic Needle (812400);
MESORAM® Hypodermic Needle (812402)

Indications for Use *(Describe)*

The MESORAM® Hypodermic Needles are intended to inject fluids intradermally.

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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This 510(k) Summary was prepared in accordance with 21 CFR 807.92

1. Submitter

Applicant: PromaMedical Inc.
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Application Correspondent: Michael Nilo
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Date Prepared: 05 October 2023

2. Device Information

Trade Name: MESORAM® Hypodermic Needles

Common Name: Hypodermic Needle

Device Classification: Name: Needle, Hypodermic, Single Lumen
Regulation No.: 21 CFR 880.5570
Product Code: FMI – Needle, Hypodermic, Single Lumen
Class: II
Classification Panel: General Hospital

3. Predicate Device Information

Trade Name: Meso-Relle (AAL34, AAL36, AM30G)

510(k) Number: K161255

Common Name: Hypodermic Needle

Device Classification: Name: Needle, Hypodermic, Single Lumen
Regulation No.: 21 CFR 880.5570
Product Code: FMI – Needle, Hypodermic, Single Lumen
Class: II
Classification Panel: General Hospital

4. Device Description

MESORAM hypodermic needles are single lumen hypodermic needles that will inject fluids into the intradermal space. The device consists of an AISI 304 stainless steel tube that is sharpened at one end, with the other end joined to a female connector (luer) designed to mate with a male connector.

MESORAM hypodermic needles are available in gauges 27 G, 30 G, 32 G, and 33 G, with varying needle lengths and outer diameters. The needles feature a protective tip cover which is formed of rigid polypropylene.

5. Intended Use

MESORAM hypodermic needles are intended to inject fluids intradermally.

6. Comparison of Technical Characteristics with the Predicate Device

There are no differences in the technological characteristics between the proposed device and the predicate (K161255) device. The proposed and predicate devices have identical indications for use. The proposed device is made from the same supplier as the predicate device and shares the same materials, design, and sterilization method as the predicate device. **Table 1** provides a technological comparison between the proposed and predicate devices.

Table 1: Comparison of Subject Device to Predicate Device

Category	**Subject Device** MESORAM® Hypodermic Needle	**Predicate Device** Meso-Relle (AAL34, AAL36, AM30G)	**Comments**
Manufacturer	PromaMedical Inc. 4585 Ponce De Leon Blvd., Suite 719 Miami, FL 33146 USA	Biotekne SRL Via Della Bastia 9 Casalecchio De Rino, Italy 40033	N/A
510(k) Number	N/A	K161255	N/A
Regulation Number	880.5570	880.5570	Identical
Product Code	FMI	FMI	Identical
Classification Name	Needle, Hypodermic, Single Lumen	Needle, Hypodermic, Single Lumen	Identical
Indication	Intended to inject fluids intradermally	Intended to inject fluids intradermally	Identical
Needle Material	AISI 304 Stainless Steel	AISI 304 Stainless Steel	Identical
Needle Lengths	4-25 mm	4-12 mm	Substantially Equivalent: While the MESORAM needles offer longer lengths, they were evaluated to the same testing standards as the predicate device and raise no new questions of safety or effectiveness.

Category	**Subject Device** MESORAM® Hypodermic Needle	**Predicate Device** Meso-Relle (AAL34, AAL36, AM30G)	**Comments**
Needle Gauges	27-33 G	30 G	Substantially Equivalent: While the MESORAM needles offer larger gauges (32 & 33 G), they were evaluated to the same testing standards as the predicate device and raise no new questions of safety or effectiveness.
Needle Tip Configurations	Triple sharpened, non-coring	Triple sharpened, non-coring	Identical
Hub Material	Polypropylene (MG03MA)	Polypropylene (MG03MA)	Identical
Needle Cover Material	Rigid cover, polypropylene J801	Rigid cover, polypropylene or polypropylene / ethylene copolymer rigid cover, polyethylene	Substantially Equivalent: Subject device is identical to one of the configurations of the predicate device
Adhesive (Needle to Hub bond)	Epoxy	Epoxy	Identical
Lubricant	Medical grade silicone oil	Medical grade silicone oil	Identical
Sterilization Method	EtO	EtO	Identical
Biocompatibility Conformance	ISO 10993-1	ISO 10993-1	Identical
Performance Testing Conformance	ISO 7864:2016 ISO 9626:2016 ISO 594-1:1986	ISO 7864:2016 ISO 9626:2016 ISO 594-1:1986	Identical

7. Performance Standards

FDA has established performance standards which apply to this device, and the proposed device was evaluated per those standards:

- ISO 594-1:1986 *Conical Fittings with a 6% (Luer) Taper for Syringes, Needles, and Certain other Medical Equipment*
- ISO 7864-2:2016: *Sterile Hypodermic Needles for Single Use – Requirements and Test Methods*
- ISO 9626:2016: *Stainless Steel Needle Tubing for the Manufacture of Medical Devices – Requirements and Test Methods*

8. Summary of Non-Clinical Testing

The MESORAM Hypodermic Needles met all in-vitro acceptance criteria as set forth in the consensus standards mentioned as well as the April 1993 FDA Document *Guidance on the Content of Premarket Notification [501(k)] Submissions for Hypodermic Single Lumen Needles*.

Biocompatibility testing performed on the needles included:

- Cytotoxicity (ISO 10993-5, ISO 10993-12)
- Sensitization (ISO 10993-10)
- Irritation / Intracutaneous Reactivity (ISO 10993-10)
- Acute Systemic Toxicity (ISO 10993-11)
- Indirect Hemolysis (ISO 10993-4)

All samples met the biocompatibility acceptance criteria.

The sterility of the MESORAM Hypodermic Needles is assured by means of a validated sterilization method complying with the recognized consensus standard AAMI/ANSI/ISO 11135:2014 *Sterilization of Health Care Products – Ethylene Oxide – Requirements for the Development, Validation, and Routine Control of a Sterilization Process for Medical Devices*.

9. Summary of Clinical Testing

No clinical data were required for this submission.

10. Conclusion

The MESORAM Hypodermic Needles have the same indications for use and share the identical technological characteristics as the predicate device. The results of performance testing show the proposed device is substantially equivalent to the predicate in performance as all test results show conformity to recognized consensus standards for this device type. Based on their intended use, technological characteristics, and performance testing results, the proposed MESORAM Hypodermic Needles can be considered substantially equivalent to the predicate.