August 6, 2019

Progressive Medical, Inc.
% David Mullis
Regulatory Consultant
Mullis & Associates, Inc.
367 Pleasant Valley Rd., P.O. Box 39
Good Hope, Georgia 30641

Re: K191295
Trade/Device Name: Percutaneous Introducer Needle
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: April 30, 2019
Received: May 14, 2019

Dear David Mullis:

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 (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 located 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.

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

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

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191295

Device Name
PMIPIN15 Percutaneous Introducer Needle (5Fr)

Indications for Use *(Describe)*

Introducer for Endoscopic/Laparoscopic procedures.

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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6. 510(k) Summary

Submitter: Progressive Medical, Inc.
997 Horan Drive
Fenton, MO 63026
Establishment Registration Number: 300236238

Contact: David W. Mullis, Jr., Ph.D., RAC, FRAPS
Regulatory Consultant
Mullis & Associates, Inc.
367 Pleasant Valley Rd., P.O. Box 39
Good Hope, GA 30641
Phone: 770-722-6413
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Submission Date: April 30, 2019

Trade Name: PMIPIN15 Percutaneous Introducer Needle (5 Fr)

Common Name: Introducer

Regulation: 876.1500

Classification: Class II

Product Code: GCJ

Panel: General & Plastic Surgery

Medical Specialty: Gastroenterology/Urology

Predicate Devices: Ranfac Percutaneous Introducer PIN-15, K951090

Device Description: The PMIPIN15 Percutaneous Introducer Needle is a single-use, disposable EO sterilized device made of 304 stainless steel with a luer hub made of polycarbonate. The introducer sheath is 5 Fr and manufactured from low density polyethylene. The device is manually inserted by the physician during endoscopic and/or laparoscopic procedures.

Indication for Use: Introducer for Endoscopic/Laparoscopic procedures.

Substantial Equivalence:

The PMIPIN15 Percutaneous Introducer Needle (5 Fr) is substantially equivalent to the Ranfac PIN-15 Introducer that is

legally marketed in the United States. Each device has the same indication use and is manually inserted by the physician. Both devices have common design specifications and materials. The PMIPIN15 Percutaneous Introducer Needle is a single use, disposable, EO sterilized device made of 304 stainless steel with a luer hub made of polycarbonate. Its 5 Fr introducer sheath is manufactured from low density polyethylene which is the same material as its predicate. Both the PMIPIN15 and the PIN-15 have a protective sleeve made of low density polyethylene.

Comparison

	New Device	Predicate Device	Comment
Product Name	PMIPIN15 (5 Fr) Percutaneous Introducer Needle	Ranfac PIN-15 Percutaneous Introducer Needle	
510(k) Number	K191295	K951090	
Company	Progressive Medical, Inc.	Ranfac Corp.	
Indication for Use	Introducer for Endoscopic/ Laparoscopic procedures	Introducer for Endoscopic/ Laparoscopic procedures	Same
Classification Name	Laparoscope, General & Plastic Surgery	Laparoscope, General & Plastic Surgery	Same
Common Name	Introducer Needle	Introducer	
Product Code	GCJ	GCJ	Same
Regulatory Class	Class II	Class II	Same
Regulation #	876.1500	876.1500	Same
Sterility	Yes	Yes	Same
Sterilization Method	EO	EO	Same
Single Use	Yes	Yes	Same
Lengths/Sizes	**Needle Gauge:** 15 **Needle Length:** 116 mm **Introducer length:** 104.4 mm **Introducer Diameter:** 5 Fr	**Needle Gauge:** 15 **Needle Length:** 116 mm **Introducer length:** 104.4 mm **Introducer Diameter:** 5Fr	Same

Materials	**Needle:** 304 Stainless Steel **Handle:** Low Density Polyethylene **Female Luer Hub:** Polycarbonate **Introducer:** Low Density Polyethylene **Protective Sleeve:** Low Density Polyethylene	**Needle:** 304 Stainless Steel **Handle:** Low Density Polyethylene **Female Luer Hub:** Polycarbonate **Introducer:** Low Density Polyethylene **Protective Sleeve:** Low Density Polyethylene	Same
Mode of Operation	Manual Insertion	Manual Insertion	Same
Package	Tyvek/Plastic Pouch	Tyvek/Plastic	Same
Biocompatible	Yes	Yes	Same
Shelf Life	2 yr.	5 Yr.	
Bioburden	Yes	Unknown	

Non-clinical Testing: A series of preclinical tests were performed to assess the safety and performance of the PMIPIN15 Percutaneous Introducer Needle (5Fr) including biocompatibility physical and mechanical performance.

The following biocompatibility and safety tests were conducted in compliance with ISO standards:

- Cytotoxicity Test: ISO10993-5
- Dermal Sensitization Guinea Pig Maximization Tests: 1SO10993-10
- Intracutaneous Test: ISO10993-10
- Ethylene Oxide Sterilization Validation: ISO 11135:2014
- Package Validation: ASTM 2096-11, ASTM F1186/1886M-16, ASTM F88/F88M-15, ASTM D5276-98
- Shelf Life Validation: ASTM F-1980-16

Physical measurements and visual inspection of the PMIPIN15 and Ranfac PIN-15 were performed to confirm similarity in design and materials. Performance evaluation, in compliance with ISO 11070:2014(E), was performed for strength of union of needle and hub as well as force at break. Needle penetration testing was conducted by an independent lab in accordance with ISO 11070:2014(E). Accelerated aging testing was conducted per ASTM F1980-16. Package integrity testing to assess seal strength and leak detection were performed in conformance with ASTM standards, as referenced above. The PMIPIN15 Percutaneous Introducer Needle (5 Fr) met its design specifications.

Conclusion:	Based on preclinical testing results, indications for use, performance evaluation, design specifications, and comparison with the predicate device, the PMIPIN15 Percutaneous Introducer Needle (5Fr) is substantially equivalent to its referenced predicate.