August 29, 2023

Premium Medical Technology LLC
Kuowei Chang
Managing Director
1377 Main Street
2nd Floor
Waltham, Massachusetts 02451

Re: K231407
Trade/Device Name: StarFin
Regulation Number: 21 CFR 884.1730
Regulation Name: Laparoscopic Insufflator
Regulatory Class: II
Product Code: HIF, GCJ
Dated: July 25, 2023
Received: August 1, 2023

Dear Kuowei Chang:

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,

Jason Roberts -S

Jason R. Roberts, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231407

Device Name
StarFin

Indications for Use *(Describe)*
The StarFin device is intended for percutaneous insertion into the peritoneal cavity for the purpose of insufflation with carbon dioxide to establish pneumoperitoneum for laparoscopic procedures prior to the placement of trocars. The StarFin device is also used for suture capture, passing, externalization and internalization for wound closure after laparoscopic surgery.

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.

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510(K) Summary

1. **Submitter Information**

   - **510(K) Submitter:**
     Premium Medical Technology LLC
     1377 Main Street, 2nd Floor
     Waltham, MA 02451-1624, USA
   - **Contact:**
     Kuowei Chang, Ph.D.
     Chief Scientific Officer
     Phone: 1-781-891-4201
     Email: kchang@PremiumMedTech.com
   - **Date Prepared:**
     August 28, 2023

2. **Device Information**

   Name: StarFin
   Model: StarFin-120
   Common Name: Veress needle and Endoscopic Suture Passer
   Regulation Number: 21 CFR 884 1730
   Regulation Name: Laparoscopic Insufflator
   Product Code: HIF and GCJ
   Regulatory Class: Class II

3. **Predicate Devices**

   510(K): K193339
   Device Name: GTK Veress Needle

   510(K): K954853
   Device Name: Endo-Close™ Auto-Suture™ Trocar Site Closure Device

   The predicates have not been subject to a design-related recall

4. **Device Description**

The subject device is a single-use, sterile, laparoscopic needle that is used for percutaneous introduction of a hollow stylet into the abdomen for gas insufflation and establishment of pneumoperitoneum prior to abdominal endoscopy and for closure of trocar site wounds with suture threads.

The subject device is equipped with a stainless steel cannular consisting of a beveled needle point for cutting through tissues. Inside the cannula, there is a spring-loaded inner stylet with a rounded blunt tip used for puncture protection. The hollow stainless steel inner stylet provides passing carbon dioxide gas to create pneumoperitoneum. The inner stylet tip is designed for suture capture, passing, externalization, and internalization for wound closure after laparoscopic surgery.

The environment of use is professional healthcare.

5. Indication for Use

The StarFin device is intended for percutaneous insertion into the peritoneal cavity for the purpose of insufflation with carbon dioxide to establish pneumoperitoneum for laparoscopic procedures prior to the placement of trocars. The StarFin device is also used for suture capture, passing, externalization and internalization for wound closure after laparoscopic surgery.

6. Comparison of the Technological Characteristics

Table below provides comparison of technological characteristics between Subject Device and Predicate Devices:

Items	Subject Device Dual-Function	Predicate K193339 Single-Function	Predicate K954853 Single-Function	Comments
Product Description & Intended Use	Combination Veress Needle & Trocar Site Wound Closure	Veress Needle	Trocar Site Wound Closure	Same Same
Model Number	StarFin-120	VN-120	173022	/
Manufacturer	Premium Medical Technology LLC	Guangzhou T.K Medical Instrument Co. Ltd.	Covidien LLC	/
Classification	Class II	Class II	Class II	Same
Product Code	HIF & GCJ	HIF & FHO	GCJ	/
Cutting Point	C=Bevel	C=Bevel	C=Bevel	Same

Spring loaded (Inner Stylet)	**Yes**	**Yes**	**Yes**	**Same**
Valve Controlled	**Yes**	**Yes**	**No**	**Same**
Needle Material	**304 Stainless Steel**	**304 Stainless Steel**	**304 Stainless Steel**	**Same**
Handle Material	**polyphenylsulfone**	**polycarbonate**	**ABS plastic and polyethylene**	**Different**
Shape of the suture passer	**A needle with a dull, blunt hook**	**N/A**	**A needle with a dull, blunt hook**	**Same**
Sterilization	**Ethylene Oxide**	**Ethylene Oxide**	**Ethylene Oxide**	**Same**

The subject and predicate devices have the same intended use. The subject device's intended use is the combination of the intended use of the predicate devices. The subject and predicate device have different technological features, including the needle diameter, length, and handle material. These technological differences do not raise different questions of safety or effectiveness.

7. Non-Clinical Performance Data

The following data were provided in support of the substantial equivalence determination.

a. Biocompatibility Test

The stainless-steel outer cannula and inner stylet of the subject device are the components in contact with human tissue for less than 24-hours. The following tests were completed and met the requirements, in accordance with:

ISO 10993-5, 2009, Cytotoxicity Test
ISO 10993-10, 2021, Maximization/Sensitization Test
ISO 10993-10, 2021, Irritation/Intracutaneous Reactivity Test
ISO 10993-11, 2017, Acute Systemic Toxicity Test
ISO 10993-11, 2017/USP<151>, Material Mediated Pyrogenicity Test

b. Sterilization Validation

The sterilization validation was performed and verified according to ISO 11135:2014. The EO and ECH residual of the subject device were evaluated and verified in accordance with ISO10993-7:2008.

c. Bench Performance Tests

The subject device was tested to demonstrate it meets stated performance expectations and compared with the predicate devices. The tests included appearance, size, gas flow rate, gas leak rate, puncture force, suture retention force, stylet pull strength. The tests were also conducted with aged sample (accelerated

aging equivalent to 1 year per ASTM F1980) and compared with non-aged samples to demonstrate 1 year shelf-life.
The simulated use of subject device was evaluated and compared with the predicate devices on an artificial skin/fascial sample by qualified and trained laparoscopic surgeons.

8. Conclusions

The non-clinical performance data demonstrate that the subject device is as safe and effective as the predicate devices and support the subject device is substantially equivalent to the predicate devices.