DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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July 6, 2016

POP Medical Solutions
Paul Dryden
Regulatory Consultant
27 Habarzel St.
Tel Aviv, 6971039 IL

Re: K160569
Trade/Device Name: NeuGuide
Regulation Number: 21 CFR 884.4530
Regulation Name: Obstetric-Gynecologic Specialized Manual Instrument
Regulatory Class: Class II
Product Code: PBQ
Dated: June 10, 2016
Received: June 13, 2016

Dear Paul Dryden,

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160569

Device Name
NeuGuide

Indications for Use *(Describe)*
NeuGuide is indicated for attaching sutures to ligaments of the pelvic floor.

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) summary

1. Submitter

Submitted by: Pop Medical Solutions Ltd.
Habarzel St. 27, Tel Aviv 6971039, Israel
Phone: +972-3- 7684948
Fax: +972-3- 7684941

Official contact: Guy Ohad, CEO

Date prepared: 10-June-2016

2. Device

Trade name: NeuGuide

Common name: Pelvic ligament fixation system

Regulation/ Classification name: 21 CFR 884.4530 - Obstetric-gynecologic specialized manual instrument

Product Code: PBQ - Fixation, non-absorbable or absorbable, for pelvic use

Regulatory class: II

3. Predicate device

Predicate device: K120831 Neomedic Anchorsure

4. Device description

The NeuGuide™ device is indicated for anchoring sutures to ligaments of the pelvic floor. It is a single use instrument, supplied sterile and pre-loaded. The NeuGuide device comprises three elements, the anchor-suture unit, an applicator, and a thimble with work channel.

Component	Characteristics	Material
Anchor	Diameter 2.0 mm Length 9.0 mm	Nitinol
Suture	USP 0 Diameter 0.4 mm Length 740 mm	Polypropylene monofilament
Applicator Shaft	Diameter 2.5 mm Length 284 mm	Stainless steel AISI 316L
Applicator Handle	Base diameter 28mm Body diameter 6 - 14.6mm	POM-C Tecaform AH MT White Polycarbonate
Thimble	Working channel inner diameter 2.6 mm	DSM Somos WaterShedXC 11122

5. Indications for use

NeuGuide is indicated for attaching sutures to ligaments of the pelvic floor.

6. Comparison with the predicate device

Both the subject and predicate devices are indicated for attaching sutures to ligaments of the pelvic floor.

The basic technological characteristics of the NeuGuide are the same as those of the predicate. Both are:

- Manual delivery of an anchor-suture implant via applicator handle
- Single use, supplied sterile and pre-loaded
- Fixation in the ligament utilizing a non-absorbable suture tied to an anchor

The main technological differences between the NeuGuide and the predicate include the anchor shape (two deployable spurs on the NeuGuide vs. four stationary barbs on the predicate), anchor material (Nitinol in the NeuGuide vs. PEEK in the predicate), and the use of a thimble with the NeuGuide (no thimble is utilized with the predicate). These differences do not raise new types of safety or effectiveness questions. These differences have been evaluated in performance testing, including MRI compatibility, biocompatibility, corrosion testing, pull out force, and deployment force.

7. Performance data

The NeuGuide has undergone and successfully passed performance testing as follows:

Test	Details	Conclusions
Biocompatibility ISO 10993-1 ISO 10993-5 ISO 10993-6 ISO 10993-10 ISO 10993-11 ISO 10993-18	Cytotoxicity, intracutaneous reactivity , sensitization, implantation, acute systemic toxicity, Extractable and Leachable testing with risk based assessment of the findings	NeuGuide was demonstrated to be biocompatible
Corrosion Anchor - ASTM F2129 Applicator - ASTM F1089	Anchor - cyclic potentiodynamic polarization Applicator – Boil test, copper sulfate corrosion test	Both tests were passed according to predefined acceptance criteria
Suture testing USP 37-NF32 USP 37-NF32 <881> USP 37-NF32 <861>	Anchor to suture attachment force Suture diameter Suture tearing force	Pass according to predefined acceptance criteria
Anchor strength and fixation forces	Anchor spurs shear force Anchor deployment Anchor pull-out force in porcine ligament in situ	Pass according to predefined acceptance criteria
Functional testing	Test entire system together for functionality	Pass according to predefined acceptance criteria

MRI compatibility- 3 Tesla	Magnetic field interactions MR related heating Artifact test MR conditional labeling	The NeuGuide™ Anchor was demonstrated to be MR Conditional. A patient with this device can be scanned safely, immediately after placement under conditions specified in the labeling
Sterilization validation	ETO validation to SAL 10^{-6} LAL endotoxin pyrogenicity ETO residual levels	Pass according to predefined acceptance criteria
Packaging validation	Sterile barrier validation at T_0 and after 1 year shelf life	Testing supports 1 year shelf life.
Shelf life validation	Functional validation of product after 1 year shelf life	Testing supports 1 year shelf life.
Transportation validation	Functional testing of device after transportation	Pass according to predefined acceptance criteria

8. Conclusions

NeuGuide is substantially equivalent to the predicate device.