DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 26, 2016

Vesocclude Medical, LLC
Mr. Freddy Cannady
President and Founder
7429 ACC Blvd., Suite 101
Raleigh, NC 27617

Re: K152082
Trade/Device Name: Vesocclude Polymer Ligating Clip
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: Class II
Product Code: FZP
Dated: December 5, 2015
Received: January 28, 2016

Dear Mr. Cannady:

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" (21CFR 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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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)*
K152082

Device Name
Polymer Ligating Clip

Indications for Use *(Describe)*
Intended Use: The Vesocclude Polymer Ligation Clips are intended for use in procedures involving ligation of vessels or tissue structures. Surgeons should apply the appropriate size clip for the size of the vessel or tissue structure to be ligated such that the clip completely encompasses the vessel or tissue structure.

Contraindications: Vesocclude polymer ligation clips are not intended for use as a fallopian contraceptive tubal occlusion device. Vesocclude polymer ligation clips are contraindicated for use in ligating the renal artery during laparoscopic donor nephrectomies.

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
(Per 21 CFR 807.92)

Date: February 13th 2016

Company Name: Vesocclude Medical, LLC

Company Address: 7429 ACC BLVD
Suite 101
Raleigh, NC 27617

Contact Person: Freddy Cannady
President and Founder
919-201-3142

Device Trade Name: Vesocclude™ Polymer Ligating Clip

Regulation Name: Implantable Clip

Regulation Number: 21 CFR 878.4300

Product Code: FZP

Predicate Device: Teleflex Medical Hem-o-lok® Ligating Clips (K030311, K003337, K993157, K902108)

Device Description: The Vesocclude™ ligating clips are non-absorbable, non-active implantable devices to be used for ligation of vessels and tissue structures. The clips are made of acetal homopolymer and are offered in three sizes; medium/large, large and x-large. Each clip size is compatible with a corresponding clip applier that may be designed for either general or endoscopic procedures. The clips are supplied in quantities of six according to size in color coded cartridges that are prepackaged sterile and single-use.

Intended Use: The Vesocclude Polymer Ligation Clips are intended for use in procedures involving ligation of vessels or tissue structures. Surgeons should apply the appropriate size clip for the size of the vessel or tissue structure to be ligated such that the clip completely encompasses the vessel or tissue structure.

Contraindications: Vesocclude polymer ligation clips are not intended for use as a fallopian contraceptive tubal occlusion device. Vesocclude polymer ligation clips are contraindicated for use in ligating the renal artery during laparoscopic donor nephrectomies.

Technological Characteristics: The technological characteristics of the proposed device are similar or the same as those of the predicate devices. The shape, sizes offered, material, method of application and mechanical function of the Vesocclude clip are the same as the predicate device.

Performance Data (Nonclinical): Performance testing consisting of dimensional analysis, clip applier compatibility, post aging performance and functional testing for resistance to leakage and migration were completed and demonstrate equivalence to the predicate device. And biocompatibility testing in accordance to ISO 10993-1 standards was conducted.

Statement of Substantial Equivalence: The Vesocclude™ Polymer Ligating Clips are substantially equivalent to their predicate device; the Teleflex Medical Hem-o-lok® Ligating Clips, based upon similarities in intended use, design, principles of operation and performance specifications.