DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 25, 2016

Nanova Biomaterials, Inc.
Mr. Andrew Ritts
Senior Research Scientist
3806 Mojave Ct.
Columbia, MO 65202

Re: K151943
Trade/Device Name: Vas-Q-Clip
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: Class II
Product Code: FZP
Dated: February 23, 2016
Received: February 26, 2016

Dear Mr. Ritts:

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)*
K151943

Device Name
Vas-Q-Clip^TM

Indications for Use *(Describe)*
Vas-Q-Clip^TM ligating 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.

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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Section 5. 510(k) Summary

1) Submitted By:

Nanova Biomaterials, Inc
3806 Mojave Ct
Columbia, MO 65202
USA
573-875-6682

Contact Person: Andrew Ritts Phone: (573) 823-3114
Secondary Contact: Richard Lebens Phone: (573) 875-6682

2) Establishment Registration No.: 3011430871

3) Date Prepared: December 14, 2015

4) Device Trade Name: Vas-Q-Clip™

5) Device Common Name: Ligation Clip

6) Device Classification Name/ Regulation #/Product Code: Implantable Clip/ 878.4300/ FZP

7) Classification Panel: General and Plastic Surgery

8) Device Class: Class II

9) Predicated Devices:
Vas-Q-Clip™ is believed to be substantially equivalent to Hem-O-lok® Ligating Clip (K993157).

10) Indication for Use:
Vas-Q-Clip™ ligating 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.

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Section 5. 510(k) Summary - Cont.

11) Device Description:

Nanova Biomaterials Inc.'s **Vas-Q-Clip*™*** causes hemostasis through vessel ligation. The technological characteristics are the same as or equivalent to the predicate device. The non-absorbable polyacetal material used in the clips is the same as the predicate device and the clips are manufactured in a similar manner.

The clips are housed in a cartridge and package in a ridged plastic plaster with Tyvek coated lidding and is sold sterile. The method of sterilization is EtO with a SAL of 10^{-6}. The blisters are fitted into a carton in which the clips are sold.

12) Substantial Equivalence:

The document, "Guidance on the CDRH Premarket Notification Review Program, 6/30/86 (K86-3)" was used to determine substantial equivalence:

a) The applicant device has the same intended use as the 510(k) cleared predicate listed above.

b) The technological characteristics of this product are believed to be substantially equivalent as those for the predicate device. This device and its predicates are substantially equivalent in material and manufacturing methods. **Vas-Q-Clip*™*** is packaged in a similar manner to its predicate and many 510k cleared products already on the market. A summary of the comparison is shown in **Table 5.1** below.

The **Vas-Q-Clip™** outer structure including legs, bosses, hook and latch mechanism, and hinge are the same as the Hem-o-lok® design (Shape and dimensions are the same for the corresponding sizes). The only difference is the inner closure feature designated as "teeth". **Vas-Q-Clip*™*** triangular protrusions (teeth) are perpendicular to the vessel whereas the Hem-O-Lok teeth are parallel.

Vas-Q-Clip*™* has the same Intended Use as the predicate devices to which it was compared, and there are no differences in technological characteristics which raise new questions of safety and / or effectiveness. Therefore, **Vas-Q-Clip*™*** is substantially equivalent.

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Table 5.1. Technical Comparison of **Vas-Q-Clip*™*** and Hem-O-Lok® (K993157)**.**

Name	**Vas-Q-Clip*™***	Hem-O-Lok® (K993157)**.**	Comparison
Indications for use	**Vas-Q-Clip*™*** ligating 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.	Hem-O-Lok® ligating 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.	Same
Composition	Polyacetal	Polyacetal	Same
Processing	Injection Molding	Injection Molding	Same
Sterility	EtO at 10^{-6} SAL	EtO at 10^{-6} SAL	Same
Design	Triangular protrusions are perpendicular to the vessel	Triangular protrusion are parallel to the vessel	Different
Size	ML, L, XL	M, ML, L, XL	No M size
Migration Resistance	Internal Testing	Internal Testing	Higher strength
Vessel Occlusion	Internal Testing	Internal Testing	Higher pressure
Application Force	Internal Testing	Internal Testing	Higher strength
Axial Pull-Off Force	Internal Testing	Internal Testing	Higher strength
Packaging	The clips are housed in a cartridge and package in a ridged plastic plaster with Tyvek coated lidding.	The clips are housed in a cartridge and package in a ridged plastic plaster with Tyvek coated lidding.	Same

13) Non-Clinical Performance Testing:

Non-clinical testing was completed to assess its performance. Table 5.2 shows the list of tests performed. The data provided in this 510(k) submission shows that the composition is safe based on the biocompatibility risk assessment conducted and a benchtop assessment.

Table 5.2. Tests performed on **Vas-Q-Clip*™*.**

Name	**Result**
Migration Resistance	Passed
Vessel Occlusion	Passed
Application Force	Passed
Axial Pull-Off Force	Passed
USP 85 Bacterial Endoxins Test	Passed
USP 151 Rabbit Pyrogenicity Test	Passed
Material Comparison Test	Passed
ISO 10993-10 Skin Sensitization	Passed
ISO 10993-6 Local Effects After Implantation	Passed
Visual Inspection of Seal	Passed
Bubble Emission	Passed
Dye Penetration	Passed
Peel-off Seal Strength	Passed
Accelerated and Real Time Aging	Passed
Sterility	Passed

14) Clinical Performance Testing:
Clinical performance data was not included.

Conclusion:

Nanova Biomaterials Inc. believes that **Vas-Q-Clip™** is substantially equivalent to currently legally marketed products. It does not introduce new indications for use, has similar technological characteristics and does not introduce new potential hazards or safety risks.