December 20, 2019

Dannik
Olga Haberland
Regulatory Compliance
941 W Morse Blvd. Suite 100
Winter Park, Florida 32789

Re: K192711
Trade/Device Name: Dannik Titanium Ligation Clip
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable Clip
Regulatory Class: Class II
Product Code: FZP
Dated: September 19, 2019
Received: September 27, 2019

Dear Olga Haberland:

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,

Cindy Chowdhury, Ph.D., M.B.A.
Acting Assistant Director
DHT4B: Division of Infection Control
and Plastic 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)*
K192711

Device Name
DANNIK Titanium Ligation Clip

Indications for Use *(Describe)*
The DANNIK Titanium Ligation Clips is designed for the intended use of ligating blood vessels .The Clip has been specially designed to insure occlusion of vessels and prevent any slippage once applied. The clip has applications in many types of surgical procedures where hemostasis is required or radiographic marking is necessary.
Choose the size of clip to fit the procedure making certain the tissue to be occluded fits completely within the clip. The DANNIK Titanium Ligation, clip can be left in vivo without sequela as it is biologically inert.

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. Contact Information
   DANNIK
   941 West Morse Blvd.
   Suite #100
   Winter Park, Florida 32789
   Phone: (407) 745-1698
   Olga Haberland, Regulatory Compliance
   December 16, 2019

2. Device Name
   - Trade Name – DANNIK Titanium Ligation Clip
   - Common Name: Titanium Ligation Clip
   - Classification Name – Clip Implantable
   - Classification: Class II General and Plastic Surgery Devices #79 FZP, 21 CFR 878.4300

Performance Standards: Devices are manufactured according to Good Manufacturing Practices (G.M.P.), Association for Advancement of Medical Instrumentation (A.AM.I.) and American Society for Testing and Materials (A.S.T.M.) requirements and applicable Harmonized Standards ISO 13485.

Material Composition: A.S.T.M F-67 95, Grade I Titanium
I.S.O. #5832-2-93, Grade I Titanium

3. Substantially Equivalent Device
   - Legally Marketed (unmodified Devices):
     - Primary Predicate: Vitalitec International Inc Implantable Titanium Hemostatic Clip FDA 510K (K981645)
     - Additional Predicate: Weck Metal Ligating Clips (K132658)

4. Device Description

The DANNIK Titanium Ligation Clips are exclusively made of titanium and supplied in four different sizes: small, medium, medium-large, and large. Packaged in cartridge of six clip units.

The titanium used meets all requirements for A.S.T.M. specifications F-67 95 "Unalloyed Titanium for Surgical Implant Applications", Grade I and ISO 5832-2-93 and 10993 "Implants for Surgery - Metallic Materials - Part 2: Unalloyed Titanium".

This device is packaged and sterilized for single use only. Do NOT re-use, reprocess or resterilize. Discard after use with care.

Biocompatibility Conforms to ISO 10993
Prescription Only Yes
Sterilized by ETO (Ethylene Oxide)

5. Intended Use

The DANNIK Titanium Ligation Clips is designed for the intended use of ligating blood vessels. The Clip has been specially designed to insure occlusion of vessels and prevent any slippage once applied. The clip has applications in many types of surgical procedures where hemostasis is required or radiographic marking is necessary.
Choose the size of clip to fit the procedure making certain the tissue to be occluded fits completely within the clip. The DANNIK Titanium Ligation, clip can be left in vivo without sequela as it is biologically inert

6. Technological Characteristics of the Subject Device Compared to the Predicate Device

Comparison of Technological Characteristics: The titanium clip material and disposable holder material substantially equivalent to the predicate device. In function, the clips are the substantially equivalent to the predicate device as well.

Safety and Efficacy Information: Titanium is well recognized as being safe and effective for long term implantation. Millions of titanium clips are applied yearly and since inception in the 1960's attest to the wide

acceptance of this method of hemostatic and ligation control.

There are no new technologies being added to this device from the predicate, in terms of finished device functions. The device has the same intended use and application as the predicate device.

Device	DANNIK Titanium Ligation Clip	Vitalitec K981645	Weck Metal Ligating Clips K132658
Intended use	The DANNIK Titanium Ligation Clips is designed for the intended use of ligating blood vessels .The Clip has been specially designed to insure occlusion of vessels and prevent any slippage once applied. The clip has applications in many types of surgical procedures where hemostasis is required or radiographic marking is necessary. Choose the size of clip to fit the procedure making certain the tissue to be occluded fits completely within the clip. The DANNIK Titanium Ligation, clip can be left in vivo without sequela as it is biologically inert.	The VITALITEC INTERNATIONAL, INC,. Hemostatic Clip is designed for the intended use of ligating blood vessels. The clip has been specially designed to insure occclusion of vessels and prevent any slippage once applied. The clip has applications in many types of surgical procedures where hemostasis is required or radiographic marking is necessary. Choose the size of clip to fit the procedure making certain the tissue to be occluded fits completely within the clip. The VITALITEC INTERNATIONAL, INC., clip can be left in vivo without sequela as it is biologically inert.	Weck@ Ligating Clips are intended for use in procedures involving vessels or anatomic structures for which the surgeon determines ligating clips are the best choice. Surgeons should select the size, type and material of the clip based upon their experience, judgment and needs

Device Description	Titanium Ligation Clips made exclusively made of titanium	Same	Weck® Metal Ligating Clips are manufactured from medical grade titanium, tantalum or stainless steel alloys
Clip Material	Titanium The titanium used meets all requirements for A.S.T.M. specifications F-67 95 "Unalloyed Titanium for Surgical Implant Applications", Grade I and ISO 5832-2-93 and 10993 "Implants for Surgery - Metallic Materials - Part 2: Unalloyed Titanium".	Same	Medical Grade Titanium
Sterilization	Ethylene Oxide (ETO) I.S.O 11135-1	Unknown	Unknown
Prescription Only	Yes	Same	Same
Biocompatibility	Conforms to ISO 10993	Unknown	Conforms to ISO 10993
Enviromental Conditions			Weck® Metal Ligating Clips are "MR Conditional" up to and including 3-Tesla MR environments.

7. Non-Clinical Tests

The DANNIK Titanium Ligation Clips has been evaluated by our Design Engineer and through performance studies and bench testing, as attached in ANNEX F. Testing encompassed appearance, dimension, surface roughness, hardness toughness , clamping(retention) performance and corrosion resistance.

All the test results were “PASS”. The performance of Titanium Clip meets the technical standard requirements of Dannik as compared to the predicate.

8. Clinical Tests
   No Clinical trials performed on the DANNIK Titanium Ligation Clips .

9. Conclusions
   The subject device has equivalent indications for use as the predicate device. The technological characteristics, non-clinical testing and performance and bench testing of the DANNIK Titanium Ligation Clips show that the device is substantially equivalent to the predicate.