Nvision Biomedical Technologies, LLC
% Jeffrey Brittan
Consultant
Watershed Ideas Foundry
1815 Aston Ave., Suite 106
Carlsbad, California 92008

April 4, 2019

Re: K182943
Trade/Device Name: VERTEX Nitinol Staple System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: JDR
Dated: October 22, 2018
Received: October 23, 2018

Dear Jeffrey Brittan:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Daniel S. Ramsey -S
2019.04.04 14:34:48 -04'00'

FOR Mark N. Melkerson
Director
Division of Orthopedic 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182943

Device Name
VERTEX™ Nitinol Staple System

Indications for Use *(Describe)*

The VERTEX Nitinol Staple System is indicated for bone fragments and osteotomy fixation and joint arthrodesis of the hand or foot.

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

DATE PREPARED
April 2, 2019

MANUFACTURER AND 510(k) OWNER
Nvision Biomedical Technologies, Inc.
4754 Shavano Oak, Suite 101
San Antonio, TX 78249, USA
Telephone: (210) 545-3713
Fax: (866) 764-1139
Official Contact: Diana Langham, Director of Regulatory and Corporate Compliance

REPRESENTATIVE/CONSULTANT
Jeffrey Brittan
Watershed Idea Foundry
Telephone: (714) 287-6780
Email: jeffbrittan@watershedideas.com

PROPRIETARY NAME OF SUBJECT DEVICE
VERTEX™ Nitinol Staple System

COMMON NAME
Bone Staple

DEVICE CLASSIFICATION
Staple, Fixation, Bone
(Classification Regulations: 21 CFR 888.3030, Product Codes: JDR, Class: II)

PREMARKET REVIEW
ODE/DOD/Joint and Fixation Devices (JFDB2)
Orthopedic Panel

INDICATIONS FOR USE
The VERTEX Nitinol Staple System is indicated for bone fragments and osteotomy fixation and joint arthrodesis of the hand or foot.

DEVICE DESCRIPTION
The VERTEX Nitinol Staple System consists of a series of nickel titanium alloy staple implants and the instruments necessary for the treatment of pathologies of the foot and ankle. The VERTEX bone staples are made from superelastic nitinol that does not require cold storage or heating.

PREDICATE DEVICE IDENTIFICATION

The VERTEX Nitinol Staple System is substantially equivalent to the following predicates:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K142111	Novastep Arcad Compressive Osteosynthesis Staple	✓
K011716	New Deal (Integra) Uni-Clip Staple*	
K142292	BioMedical Enterprises, Inc Speed Staple	

*Additional Uni-Clip Staple clearances include K991482 and K061594

SUMMARY OF NON-CLINICAL TESTING

No FDA performance standards have been established for the VERTEX Nitinol Staple System. The following tests were performed to demonstrate safety based on recognized consensus standards and current industry practice:

- Static bending, bending fatigue, and pullout (per ASTM F564)
- Cyclic potentiodynamic polarization testing (per ASTM F2129)
- Bend and free recovery (BFR) testing (per ASTM F2082)

The results of these tests, as well as engineering analysis of device characteristics, indicate that the VERTEX Nitinol Staple System is substantially equivalent to the predicate devices.

EQUIVALENCE TO PREDICATE DEVICES

Nvision believes that the VERTEX Nitinol Staple System is substantially equivalent to the predicate devices based on the information summarized here:

The subject device has a similar design, similar dimensions, and uses similar or identical materials as the devices cleared in K142111, K011716, and K142292. The subject device also has the same intended use, as well as similar technological characteristics (low profile bone staples with toothed legs in a range of sizes) as these predicates. The Indications for Use are equivalent and these technological characteristics have undergone testing and engineering analysis to ensure the device is as safe and effective as the predicates.

CONCLUSION

Based on the testing performed, including static bending, bending fatigue, and pullout, cyclic potentiodynamic polarization, bend and free recovery as well as engineering analysis of device characteristics, it can be concluded that the subject device does not raise new issues of safety or efficacy compared to the predicate devices. The similar indications for use, technological characteristics, and performance characteristics for the proposed VERTEX Nitinol Staple System are assessed to be substantially equivalent to the predicate devices.