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

December 4, 2018

Re: K182949
Trade/Device Name: Healix™ Compression Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: October 2, 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,

Jesse Muir -S

Digitally signed by Jesse Muir -S
Date: 2018.12.04 17:14:17 -05'00'

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)*

K182949

Device Name
Healix™ Compression Screw System

Indications for Use *(Describe)*

The HEALIX Compression Screw (HCS) System is indicated for Bone Fractures, Osteotomies, Arthrodeses, Osteochondritis, and Tendon Reattachment. It is intended for, but not limited to, Hand Surgery, Orthopedic Surgery, and Podiatric Surgery but is not intended for attachment or fixation to the posterior elements (pedicles) of the spine.

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
October 2, 2018

MANUFACTURER AND 510(k) OWNER
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PROPRIETARY NAME OF SUBJECT DEVICE
HEALIX™ Compression Screw System

COMMON NAME
Bone Fixation Screw System

DEVICE CLASSIFICATION
Smooth or threaded metallic bone fixation fastener
(Classification Regulations: 21 CFR 888.3040, Product Codes: HWC, Class: II)

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

INDICATIONS FOR USE
The HEALIX Compression Screw (HCS) System is indicated for Bone Fractures, Osteotomies, Arthrodeses, Osteochondritis, and Tendon Reattachment. It is intended for, but not limited to, Hand Surgery, Orthopedic Surgery, and Podiatric Surgery but is not intended for attachment or fixation to the posterior elements (pedicles) of the spine.

DEVICE DESCRIPTION
The Healix Compression Screw (HCS) System consists of 2.0mm to 8.5mm cannulated, solid titanium alloy, headless, headed screws and specialized instrumentation. The screw system has multiple lengths depending on diameter of the screws.

PREDICATE DEVICE IDENTIFICATION
The HEALIX Compression Screw System is substantially equivalent to the following predicates:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K014154	Vilex Cannulated Bone Screw System*	✓
K081149	BioPro GO-EZ Screw System	

*Prior Vilex Cannulated Bone Screw System submissions also include K991151, K991197, and K973309

SUMMARY OF NON-CLINICAL TESTING
No FDA performance standards have been established for the HEALIX Compression Screw System. The following tests were performed to demonstrate safety based on recognized consensus standards and current industry practice:

- Torsion, driving torque, and axial pullout (per ASTM F543)
- Static and dynamic bending (per ASTM F1264)

The results of these tests, as well as engineering analysis of device characteristics, indicate that the HEALIX Compression Screw System is substantially equivalent to the predicate devices.

EQUIVALENCE TO PREDICATE DEVICES
Nvision believes that the HEALIX Compression Screw 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 K014154 and K081149. The subject device also has the same intended use, as well as similar technological characteristics (self-tapping, cannulated, headed and headless screws) as these predicates. The Indications for Use are equivalent and any minor differences in wording choices are insignificant. The solid versions of the subject screws are the same as the cannulated versions except they do not have a central cannulation; they function equivalently and do not raise additional questions of substantial equivalence. 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, dynamic bending, torsion, driving torque, and axial pullout, 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 HEALIX Compression Screw System are assessed to be substantially equivalent to the predicate devices.