May 5, 2020

Nvision Biomedical Technologies, Inc
% Jeffrey Brittan
Vice President of Product Realization
Watershed Ideas Foundry
1815 Aston Ave., Suite 106
Carlsbad, California 92008

Re: K200914
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: March 25, 2020
Received: April 6, 2020

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/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,

Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic 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)*

K200914

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
April 27, 2020

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
Orthopedic Devices

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 cannulated, solid titanium alloy, headless, headed screws and specialized instrumentation. This submission expands the Healix offering and includes longer screws ranging from 31 to 130mm in length for the 2.0 to 7.5mm diameters.

PREDICATE DEVICE IDENTIFICATION

The subject Healix Compression Screw system is substantially equivalent to the following predicates:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K182949	Healix Compression Screw System / Nvision Biomedical	✓
K014154	Vilex Cannulated Bone Screw System	
K081149	BioPro GO-EZ Screw System	

SUMMARY OF NON-CLINICAL TESTING

No FDA performance standards have been established for the Healix Compression Screw System. The following was performed to demonstrate safety per methods of the previous submission:

- Engineering analysis comparison of mechanical performance characteristics

The results of the engineering analysis 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 modification is substantially equivalent to the predicate devices. The subject implants maintain the same features as the previously cleared devices but add screw length options that are within the range of the predicates. This modification does not change the intended use or performance of the device and does not raise additional questions of substantial equivalence. These technological characteristics have undergone engineering analysis to ensure the device is as safe and effective as the predicates.

CONCLUSION

Based on the 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 options are assessed to be substantially equivalent to the predicate devices.