July 19, 2019

The Anspach Effort, Inc.
Tamara West
Regulatory Affairs Manager
4500 Riverside Drive
Palm Beach Gardens, Florida 33410

Re: K183545
Trade/Device Name: Anspach Helix Dissection Tools
Regulation Number: 21 CFR 882.4310
Regulation Name: Powered Simple Cranial Drills, Burrs, Trephines, And Their Accessories
Regulatory Class: Class II
Product Code: HBE
Dated: June 14, 2019
Received: June 17, 2019

Dear Tamara West:

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,

For Matthew Krueger
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine 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)*

Device Name
Anspach Helix™ Dissection Tools

Indications for Use *(Describe)*
Anspach Helix™ Dissection Tools are intended for cutting and shaping bone including the spine and cranium.

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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ANSPACH®

510(k) SUMMARY

I. SUBMITTER

The Anspach Effort, Inc.
4500 Riverside Drive
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USA

Registration Number: 1045834

Contact: Tamara West
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Date Prepared: June 14, 2019

II. DEVICE

Trade Name: Anspach Helix™ Dissection Tools

Common Name: Dissection Tools

Classification Information: 21 CFR 882.4310 *Drills, burs, trephines, and accessories (simple, powered)*

Regulatory Class: II

Product Code: HBE

Classification panel: Neurology

III. PREDICATE DEVICE

K113476 Dissection Tools
Owner: The Anspach Effort, Inc.

IV. DEVICE DESCRIPTION

The *Anspach Helix™ Dissection Tools* (otherwise known as burs) are part of a drill system that consists of a control console, a handpiece (motor), a control switch and various attachments and accessories. The *Anspach Helix™ Dissection Tools* are one-piece metal bone cutting and shaping devices that attach to the handpiece/attachment of a pneumatic or electric powered drilling system.

The *Anspach Helix™ Dissection Tools* are manufactured from M2 tool steel and feature a 2-fluted ball sharp cutting edge at the distal end. The proximal end, which secures the dissection tool to the handpiece of the power system, incorporates a patented Diamond Flat configuration locking mechanism.

The *Anspach Helix™ Dissection Tools* are provided sterile.

V. INDICATIONS FOR USE

Anspach Helix™ Dissection Tools are intended for cutting and shaping bone including the spine and cranium.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

	Anspach Helix™ Dissection Tools	Dissection Tools
510(k) Number	K183545	K113476
Indications for Use	Anspach Helix™ Dissection Tools are used for cutting and shaping bone including the spine and cranium.	Dissection tools are intended for cutting shaping bone including the spine and cranium.
Product Code	HBE	HBE
Class	2	2
Sterilization	Gamma irradiated	Gamma irradiated
Sterilization Assurance Level (ASL)	10^{-6}	10^{-6}
TECHNOLOGICAL CHARACTERISTICS		
Head Styles	Fluted Ball	Fluted Ball, Fluted Matchstick, Diamond Ball
Flutes	2 Flutes	2 Flutes (Matchstick) 4 – 12 Flutes (Ball)
Head Diameter	2mm – 7mm	Fluted Ball: 0.5mm – 9mm
Material	M2 Tool Steel	M2 Tool Steel, Stainless Steel, Carbide, Diamond coated
Locking mechanism	Diamond Flat Configuration	Diamond Flat Configuration
Labeling	Sterile, single-use	Sterile, single-use

Packaging Configuration	PETG tray in a sealed Tyvek pouch placed into a carton	PETG tray in a sealed Tyvek pouch
Shelf life	5 years	5 years

The predicate dissection tools (K113476) are part of an electric/pneumatic drill system and are available in many different styles and dimensions, including a fluted ball. A minor design modification was made to the head of the existing fluted ball style by offering a 2-fluted style as compared to 4 or more flutes with the predicate device. The 2-fluted style was developed to provide a dissection tool that produces less chatter and vibration while cutting than the predicate dissection tools (K113476).

The proposed *Anspach Helix™ Dissection Tools* remain identical to the predicate dissection tools (K113476) in terms of operating principles, where it attaches to the handpiece/attachment of either an electric or pneumatic drill utilizing the diamond flat locking mechanism. The indications for use, material and manufacturing remain identical to the predicate dissection tools (K113476).

The technological characteristics of the proposed *Anspach Helix™ dissection tools* are similar to those of the predicate (K113476) device in the following ways:

- Both dissection tools use a patented locking mechanism on the distal end to secure to the handpiece
- Both dissection tools are compatible with the same electric and pneumatic drill systems, including attachments
- Both dissection tools have a straight shaft and fluted ball style head, where the proposed dissection tools have 2 flutes opposed to 4 or more flutes of the predicate dissection tools
- Both dissection tools are provided sterile

As with the predicate dissection tools (K113476), the Anspach *Helix™ Dissection Tools* have no impact on the safety and effectiveness of the device or the ability to perform as intended.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing:
The *Anspach Helix™ dissection tools* are classified as external communicating devices: tissue/bone/dentin with limited patient contact (< 24 hours).

A biocompatibility evaluation was conducted for the *Anspach Helix™ Dissection Tools* per the FDA guidance document Use of International Standard ISO 10993-1. “Biological

evaluation of medical devices – Part 1: Evaluation and testing within a risk management process".
The *Anspach Helix™ Dissection Tools* are manufactured and packaged in the same manner with identical material as the predicate device (K113476). No new or additional processing steps were introduced; therefore, biocompatibility requirements have been met.

Design Control:
The following verification activities were performed to demonstrate that the device meets the performance requirements under its indications for use conditions for determination of substantial equivalence.

Test	**Test Method Summary**	**Results**
Verification Analysis - Mating Clearance & Anti-Rotation Interference	Conduct a tolerance analysis to determine that there is mating clearance and anti-rotation interference when engaged with drive spindle of EG1, XMAX, & EMAX2PLUS handpieces	The analysis shows that the design output meets the design input; the proposed Helix dissection tools drive feature meets the acceptance criteria of mating clearance and anti-rotation interference when engaged with drive spindles of EG1, XMAX, & EMAX2PLUS handpieces.
Helix Dissection Tool and Attachment Compatibility - Shaft Diameter/Shaft Length	Conduct a tolerance analysis to determine the minimum and maximum clearance between the shaft diameter of the dissection tool and inner race bearing diameter of the attachment.	Analysis was performed by evaluating all Helix dissection tools and attachment (predicate) combinations to confirm compatibility. Tolerance analysis reflects 0.0001 to 0.0007 inches of clearance between dissection tools and the attachment which is in the required range of scope with a 3/32-inch shaft diameter and the inner race bearing diameter of compatible attachments as listed in the compatibility table. Tolerance analysis reflects that the minimum length in the lock position exists, so the head will not interfere with the attachment. Tolerance analysis reflects that the tapered section of the dissection tool will not interfere with the distal bearing inner diameter of the attachment.

Helix Ball Bur Chatter/Cut and Shape Verification Report	The % chatter for each group of same-size Helix ball burs must be less than the chatter of the corresponding group of same-size predicate G1 burs, as determined by a hypothesis test with a significance level (alpha) = 0.10.	All samples met the acceptance criteria and exhibited statistically lower% chatter than the corresponding same size predicate devices with the exception of the S-25SB-HX-G1-1. For this size, while lower, the results were not statistically significant as compared to the corresponding same size predicate.
	Each Helix ball bur used to cut into the Bi-resin (simulated bone) samples and then shall be evaluated to confirm that they cut and shape bone the same as the predicate.	All samples met the acceptance criteria to cut and shape bone, the same as the predicate.
	Each Helix ball bur used to cut into the Bi-resin (simulated bone) samples and then shall be visually inspected for cutter head fracture with the acceptance criteria of the bur head intact on the cutter and not broken, the same as the predicate.	All samples met the acceptance criteria for the head of the cutter to remain intact, the same as the predicate.

The above verification activities demonstrate the Anspach Helix™ Dissection Tools perform as intended in cutting and shaping bone in the same manner as the predicate (K113476) and are compatible with existing predicate devices (K113746). Verification activities also demonstrate that select Helix designs exhibited statistically significantly lower chatter and vibration while cutting than the corresponding same size burs of the predicate devices (K113476). Based on the results of the verification activities, the proposed Anspach Helix™ Dissection Tools are determined to be substantially equivalent to the predicate devices (K113476).

No animal or clinical testing was necessary for a determination of substantial equivalence.

VII. CONCLUSIONS

The *Anspach Helix™ Dissection Tools* described in this submission have the same intended use, general design, material, technological characteristics, and principles of operation as the predicate device (K113476) and do not raise any new issues of safety or efficacy. In addition, the select 2-flute designs that are part of the marketing claims within this submission also do not raise any new issues of safety or efficacy and were found to be substantially equivalent to the predicate devices (K113476). Therefore, the proposed *Anspach Helix™ Dissection Tools* are found to be substantially equivalent to the predicate devices.