May 19, 2022

The Anspach Effort, Inc.
% Marie Ferrier
Senior Regulatory Affairs Program Lead
Synthes GmbH
Eimattstrasse 3
Oberdorf, 4436, Switzerland

Re: K220485
Trade/Device Name: Wireless Hand Control, EG1A (WIRELESS-HC), Receiver for Wireless Hand Control, EG1A (RECEIVER-HC)
Regulation Number: 21 CFR 882.4360
Regulation Name: Electric Cranial Drill Motor
Regulatory Class: Class II
Product Code: HBC, ERL
Dated: April 20, 2022
Received: April 21, 2022

Dear Marie Ferrier:

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,

Adam D. Pierce, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220485

Device Name
Wireless Hand Control, EG1A (WIRELESS-HC);
Receiver for Wireless Hand Control, EG1A (RECEIVER-HC)

Indications for Use *(Describe)*
The eG1 High Speed System is indicated for cutting and shaping bone including 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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The Anspach Effort, Inc.
eG1 Wireless Hand Control System:
Wireless Hand Control, EG1A (WIRELESS-HC),
Receiver for Wireless Hand Control, EG1A (RECEIVER-HC)

510(k) Summary

A. Device Information:

Category	Comments
Sponsor:	The Anspach Effort, Inc. 4500 Riverside Drive Palm Beach Gardens FL 33410, United States Tel: 1-561-627-1080
Correspondent Contact Information:	Mrs. Marie Ferrier Synthes GmbH Eimattstrasse 3 Oberdorf 4436, Switzerland Tel: +33(0)675765048
Device Common Name:	Wireless Hand Control System
Device Regulation & Name:	882.4360 – Electrical cranial drill motor 874.4250 – Ear, nose, and throat electric or pneumatic surgical drill
Classification & Product Code:	HBC (Class 2) – Motor, Drill, Electric ERL (Class 2) – Drill, Surgical, Ent (Electric or Pneumatic) Including Handpiece
510(k) Number:	K220485
Device Proprietary Name:	eG1 Wireless Hand Control System

Predicate Device Information:

Predicate Device:	Foot control pedals used with eG1 High Speed System
Predicate Device Manufacturer:	The Anspach Effort, Inc.
Predicate Device Common Name:	eG1 High Speed System
Predicate Device Premarket Notification #	K133604
Predicate Device Regulation & Name:	882.4360 – Electrical cranial drill motor 874.4250 – Ear, nose, and throat electric or pneumatic surgical drill
Predicate Device Classification & Product Code:	HBC (Class 2) – Motor, Drill, Electric ERL (Class 2) – Drill, Surgical, Ent (Electric or Pneumatic) Including Handpiece

B. Date Summary Prepared

May 19th, 2022

C. Description of Device

The eG1 Wireless Hand Control System is intended to be used as an optional accessory to the eG1 High Speed System (K133604) to provide an alternative method for controlling the eG1 Handpiece motor speed instead of using the existing wired foot control pedal.

The eG1 Wireless Hand Control System consists of two articles:
1) The Wireless Hand Control, EG1A (article # WIRELESS-HC) is a sterile, single-use device that snaps on the eG1 Handpiece.
2) The Receiver for Wireless Hand Control, EG1A (article # RECEIVER-HC) is a non-sterile reusable device that plugs into the eG1 Control Console.

The WIRELESS-HC sends information about the amount of pressure applied by the user on its button to the RECEIVER-HC wirelessly. The RECEIVER-HC uses this information to modulate the speed of the eG1 Handpiece motor.

D. Indications for Use

The eG1 High Speed System is indicated for cutting and shaping bone including spine and cranium.

E. Comparison of the Technological Characteristics

Characteristic	Application Device: eG1 Wireless Hand Control System K220485	Predicate Device: Foot control pedals used with eG1 High Speed System K133604	Impact on Substantial Equivalence
Company	The Anspach Effort, Inc.	The Anspach Effort, Inc.	-
Regulation Number	882.4360 – Electrical cranial drill motor 874.4250 – Ear, nose, and throat electric or pneumatic surgical drill	882.4360 – Electrical cranial drill motor 874.4250 – Ear, nose, and throat electric or pneumatic surgical drill	Identical
FDA Product Code	HBC (Class 2) – Motor, Drill, Electric ERL (Class 2) – Drill, Surgical, Ent (Electric or Pneumatic) Including Handpiece	HBC (Class 2) – Motor, Drill, Electric ERL (Class 2) – Drill, Surgical, Ent (Electric or Pneumatic) Including Handpiece	Identical
Intended Use & Indications for Use	Cutting and shaping bone including spine and cranium	Cutting and shaping bone including spine and cranium	Identical
The device controls/ function	Speed (increase/ decrease) of the handpiece motor	Speed (increase/ decrease) of the handpiece motor Depending on model: -rotation -irrigation pump	Identical (the predicate has additional functions)
Principle of operation/ Technology	The pressure on the button is transferred from the WIRELESS-HC to RECEIVER-HC wirelessly (radio signal) and transformed into an electric signal	The pressure on the pedal is transformed into an electric signal	The predicate device does not contain any wireless technology. The device **Wireless Foot control used with ELAN 4 Electro Motor System (K203739)** is used as a reference device for this application as it shares the same indications for use, function and usage of the wireless technology to transmit a signal in order to regulate the speed of the handpiece motor. The proposed device and the reference device operate in the same frequency band (2.4 GHz). Software, Wireless and Electromagnetic Compatibility testing are

			provided in this application to demonstrate the Substantial Equivalence.
Power tool compatibility	eG1 High Speed System	eG1 High Speed System	Identical
Interface with the user (user action)	Increase/ decrease the pressure on the button to increase/ decrease the speed	Increase/ decrease the pressure on the pedal to increase/ decrease the speed Depending on model: -Press the dedicated button to change rotation -Press the dedicated button to activate irrigation pump	Identical (the predicate has additional functions)
Interface with the console	Receiver plugs into the eG1 consoles (foot pedal connector port)	Cord plugs into the eG1 consoles (foot pedal connector port)	Identical
Power source	RECEIVER-HC: main power through the console WIRELESS-HC: contains a lithium coin battery	Main power through the console	Electrical Safety testing is provided in this application to demonstrate the Substantial Equivalence.
Patient contact	No direct or indirect patient contact	No direct or indirect patient contact	Identical
Sterilization/ Reprocessing	RECEIVER-HC: non sterile, reusable (cleaning only) WIRELESS-HC: sterile, single-use	Non sterile, reusable (cleaning only)	The predicate device is non sterile. Sterilization Validation is provided in this application to demonstrate the Substantial Equivalence.

F. Summary of Supporting Data

The proposed device **eG1 Wireless Hand Control System** has the same intended use, function, interface with the eG1 console and patient contact as the predicate device **Foot control pedals used with eG1 High Speed System (K133604)**. The proposed device shows some differences regarding the power source, the technology (wireless) and sterilization.

A design verification analysis was conducted to verify that the physical characteristics of the eG1 Wireless Hand Control System meet the design inputs related to the interfaces with the user, eG1 Handpiece and Console.
Design verification testing was conducted to verify the functional aspects of the proposed device.
The software of the proposed device was developed applying IEC 62304:2015 *Medical device software - Software life cycle processes*. Design verification analysis, Design verification testing and Software Validation were conducted on the proposed device firmware.
The proposed device was developed, tested and certified according to IEC 60601-1:2012 / ANSI/AAMI ES60601-1:2012 *Medical Electrical Equipment – General Requirements for*

Basic Safety and Essential Performance.
The proposed device was developed, tested and certified according to IEC 60601-1-2:2014 *Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.*
The proposed device was found compliant with applicable US FCC regulations and standards 47 CFR Part 15 Subpart B and 47 CFR § 15.247.
The radio emissions were tested according to IEC 62311:2007 *Assessment of electronic and electrical equipment related to human exposure restrictions for electromagnetic fields (0 Hz to 300 GHz).*
The WIRELESS-HC is sterilized by Ethylene Oxide. The sterilization cycle was validated according to ISO 11135:2014 *Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices.*

G. Discussion of Performance Testing

All acceptance criteria are met. The differences in technological characteristics do not raise new questions of safety or effectiveness based on results of risk-based verification and validation testing.

H. Conclusion

Following the 510(k) Decision-Making Flowchart, it is determined that the **eG1 Wireless Hand Control System** is substantially equivalent to the predicate **Foot control pedals used with eG1 High Speed System (K133604)** as there is no difference in the intended use and the differences in technological characteristics do not raise new questions of safety or effectiveness.