November 9, 2018

Aesculap, Inc.
Jessica Stigliano
Regulatory Affairs Specialist
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K172907
Trade/Device Name: ELAN 4 Air Motor System
Regulation Number: 21 CFR 882.4370
Regulation Name: Pneumatic Cranial Drill Motor
Regulatory Class: Class II
Product Code: HBB
Dated: April 2, 2018
Received: April 4, 2018

Dear Jessica Stigliano:

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,

John Marler -S

For

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine 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)*
K172907

Device Name
ELAN 4 Air Motor System

Indications for Use *(Describe)*
The ELAN 4 Air Motor System is intended for high speed cutting, sawing, and drilling of bone in the fields of Spine, ENT, Neuro, and Maxillofacial Surgery.

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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B. 510(k) SUMMARY (as required by 21 CFR 807.92)

ELAN 4 Air Motor System
November 8, 2018

COMPANY: Aesculap®®, Inc.
3773 Corporate Parkway
Center Valley, PA 18034
Establishment Registration Number: 2916714

CONTACT: Jessica Stigliano
610-984-9063 (phone)
610-791-6882 (fax)
jessica.stigliano@Aesculapimplants.com

TRADE NAME: ELAN 4 Air Motor System

COMMON NAME: Motor, drill, Pneumatic

REGULATION NUMBER: 882.4370 - Pneumatic cranial drill motor

PRODUCT CODE: HBB

REVIEW PANEL: Neurology

SUBSTANTIAL EQUIVALENCE

Aesculap®, Inc. believes that the ELAN 4 Air Motor System is substantially equivalent to the primary predicate, ELAN 4 Electro Motor System (K152960), and reference predicate, Aesculap® HiLan Motor System for Neurosurgery (K980686).

DEVICE DESCRIPTION

The ELAN 4 Air Motor System is intended for high speed cutting, sawing, and drilling of bone in the fields of Spine, ENT, Neuro, and Maxillofacial Surgery. The ELAN 4 Air Motor System is a pneumatic motor system that can be used with any sterile, pressurized gas (usually nitrogen). The system consists of several components such as wall adaptors, foot pedals, and handpieces. The foot pedal has the ability to connect various handpieces with integrated motors that contain attachments such as burrs, saw blades, and drills. The system allows for high-speed dissection at up to 80,000 RPM while also allowing low speed cutting between 1,000 and 20,000 RPM. The speed and rotation direction of the handpieces can be controlled via the foot pedal.

INDICATIONS FOR USE

The ELAN 4 Air Motor System is intended for high speed cutting, sawing, and drilling of bone in the fields of Spine, ENT, Neuro, and Maxillofacial Surgery.

TECHNOLOGICAL CHARACTERISTICS (compared to Predicate(s))

The ELAN 4 Air Motor System is substantially equivalent to the primary predicate, ELAN 4 Electro Motor System (K152960), and reference predicate, Aesculap® HiLan Motor System for Neurosurgery (K980686). The subject device is shown to be substantially equivalent and has the same performance characteristics to its primary predicate device and reference predicate device through comparison in design, principles of operation, intended use, and materials. A comparison table summarizing these characteristics can be found below.

The ELAN 4 Air Motor System offers similar components, attachments, and operating speeds when compared to the primary predicate. The main difference between the ELAN 4 Air Motor System and the ELAN 4 Electro Motor System is the source of power for the motor. The ELAN 4 Electro Motor System is operated by an electric motor, while the ELAN 4 Air Motor System is operated by a pneumatic motor. There is no software involved in the ELAN 4 Air Motor System. Similar to the devices that are subject to this submission, the reference predicate, Aesculap® HiLan Motor System for Neurosurgery (K980686) also uses a pneumatic power source.

System	**ELAN 4 Air Motor System (subject of this submission)**	**Primary predicate: ELAN 4 Electro Motor System (K152960)**	**Reference predicate: Aesculap® HiLan Motor System for Neurosurgery (K980686)**
Indications for Use	The ELAN 4 Air Motor System is intended for high speed cutting, sawing, and drilling of bone in the fields of Spine, ENT, Neuro, and Maxillofacial Surgery.	The ELAN 4 Electro motor system is intended for high speed cutting, sawing, and drilling of bone in the fields of Spine, ENT, Neuro, and Maxillofacial Surgery.	Aesculap's HiLan Motor System for Neurosurgery is a pneumatic motor system intended for use in surgical procedures to provide power to operate removable cutting tools or drill bits on a patient's skull. It is indicated for use in neurosurgery.
Motor			
Power	Pneumatic	Electric	Pneumatic
High speed motor Min/Max	10,000/ 80,000 rpm	10,000/ 80,000 rpm	Max: 90,000 rpm
Low speed motor Min/Max	1,000/ 20,000 rpm	1,000/ 20,000 rpm	Max: 75,000 rpm
Motor rotation High speed	Right hand/Clockwise	Left and right hand rotation	Left and right hand rotation
Low speed	Left and right hand rotation	Left and right hand rotation	Left and right hand rotation
Materials	PEEK and Stainless Steel	PEEK and Stainless Steel	Stainless Steel
Features			
Control mechanism for speed	Foot Pedal	Foot Pedal	Foot Pedal

Ability to connect various Handpieces	Yes	Yes	Yes
Footswitch connections	1	1	1

PERFORMANCE DATA

Design Verification

Test	Test Method Summary	Results
Ensuring the function between two service intervals - Motor hose with manual control	Demonstrate functionality, performance features and the safety of the product based on the intended use within a service / Maintenance interval of (one year).	Pass: All requirements met
Ensuring the function between two service intervals for perforator motor	Demonstrate functionality, performance features and the safety of the product based on the intended use within a service / Maintenance interval of (one year).	Pass: All requirements met
Ensuring the function between two service intervals - ELAN 4 AIR Micros-Sagittal Saw	Demonstrate functionality, performance features safety of the product	Pass: All requirements met
Ensuring the function between two service intervals - ELAN 4 AIR Micro-Reciprocating Saw	Demonstrate functionality, performance features safety of the product	Pass: All requirements met
Ensuring the function between two service intervals - ELAN 4 air high speed Handpiece	Demonstrate functionality, performance features and the safety of the product based on the intended use within a service / Maintenance interval of (one year).	Pass: All requirements met
Verification of ELAN 4 Air Foot Control	Simulation of an application of one year for the detection of functionality, Performance and safety of the product	Pass: All requirements met

Biocompatibility

The materials in the ELAN 4 Air Motor System are exactly the same materials used in the ELAN 4 Electro Motor System. There have been no materials changes since the clearance of the ELAN 4 Electro Motor System (K152960). The ELAN 4 Air Motor System materials and biocompatibility conform to the following standards;

ISO 10993-1: Evaluation and testing within a risk management process
ISO 7153-1: Surgical instruments -- Metallic materials -- Part 1: Stainless steel

Biocompatibility testing within this submission includes cytotoxicity and hemolysis testing. The biocompatibility test results for cytotoxicity and hemolysis yielded a non-toxic response. Other biocompatibility endpoints were leveraged through a risk assessment.

CONCLUSION

The design verification and biocompatibility information along with a comparison between the technology, materials and intended use for the ELAN 4 Air Motor System and the predicate devices demonstrate that the ELAN 4 Air Motor System is as safe, as effective, and performs as well as the predicate devices. The design verification, biocompatibility information and technological comparison demonstrates that the ELAN 4 Air Motor System is substantially equivalent to the predicate devices.