August 24, 2021

Aesculap Inc.
Kathy Racosky
Project Manager I
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K203739
Trade/Device Name: ELAN 4 Electro Motor System
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: July 28, 2021
Received: July 28, 2021

Dear Kathy Racosky:

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)*
K203739

Device Name
ELAN 4 Electro Motor System

Indications for Use *(Describe)*
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.

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 (as required by 21 CFR 807.92)

ELAN 4 Software V3.00, Wireless Foot Control, Drill and Attachments
August 24, 2021

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

CONTACT: Kathy A. Racosky
610-984-9291 (phone)
610-791-6882 (fax)
kathy.racosky@aesculap.com

TRADE NAME: ELAN 4 Electro Motor System

COMMON NAME: Drills, Burrs, Trephines & Accessories (Simple, Powered)

CLASSIFICATION: Class II

CLASSIFICATION NAME: Powered simple cranial drills, burrs, trephines and their accessories

REGULATION NUMBER: 882.4310

PRODUCT CODE: HBE

Predicate device
Aesculap ELAN 4 Electro Motor System, K152960.
Reference device
Aesculap Microspeed Uni Motor System, K053526

Indications for Use
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.

Device description
The ELAN 4 Software V3.00, Wireless Foot Control, Drill and Attachments are designed for use with the ELAN 4 Electro Motor System (K152960). The ELAN 4 Electro Motor System is an electrical motor system consisting of a control unit with different sizes and types of hand-pieces, each containing its own integrated motor, and attachments such as burrs, saw blades, drills, etc.

The Control Unit of the ELAN 4 Electro Motor System houses the system software. The ELAN 4 Software V3.00 provides support for the ELAN 4 Wireless Foot Control and ELAN 4 Drill. The ELAN 4 drill is a pistol type hand-piece designed specifically to accept various ELAN 4 attachments.

Technological characteristic (compared to Predicate(s))

The ELAN 4 Software V3.00, Wireless Foot Control, Drill and Attachments are substantially equivalent to the predicate, ELAN 4 Electro Motor System (K152960) and the reference predicate MicroSpeed Uni Motor System (K053526). The subject device is shown to be substantially equivalent and has the same performance characteristics to the primary predicate device through comparison in design, principles of operation and indications for use. The subject device offers similar components, operating speeds, and power sources as the predicate device. The proposed device has some differences in technological features in comparison to the predicate device. The proposed device has a wireless foot control versus the plug in foot control for the predicate device. The subject device is manufactured from Titanium, PEEK and Stainless Steel whereas the predicate device is made from PEEK and Stainless Steel. Similar to the devices that are subject to this submission, the reference predicate, is manufactured from Titanium. The subject device has a permanently attached motor cable when compared to the plug in motor cable of the predicate device. The device characteristics comparing the ELAN 4 Software V3.00, Wireless Foot Control, Drill and Attachments to the predicate device are summarized in the substantial equivalence comparison table.

System	**ELAN 4 Electro Motor System**	**Predicate ELAN 4 Electro Motor System**	**Reference Device Microspeed Uni Motor System**
K#	K203739	K152960	K053526
Indications for Use:	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.	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.	Microspeed Uni is intended for high speed cutting, sawing, drilling and manipulation of soft tissue and bone in the fields of Spine, ENT, Neuro, and Maxillofacial Surgery.
Control Unit:			
Software version	3.00	1.03	N/A
Foot Control:			
Type	Wireless	Plugs into control unit	Plugs into control unit
Activates motor of hand-piece	Yes	Yes	Yes
Controls	Speed, rotation and irrigation pump	Speed, rotation and irrigation pump	Speed, rotation and irrigation pump
Hand-piece:			
Type	Drill	Various	Various
Integrated motor	Yes	Yes	Yes
Motor cable	Permanent	Separate cable	Separate cable
Controls speed and rotation	Yes	No	No
Attachments	Yes	No	Yes
Motor:			
Low speed motor Min/Max	1,000/ 20,000 rpm	1,000/ 20,000 rpm	3,000 rpm / 40,000 rpm

System	ELAN 4 Electro Motor System	Predicate ELAN 4 Electro Motor System	Reference Device Microspeed Uni Motor System
K#	K203739	K152960	K053526
Low speed	Left and right hand rotation	Left and right hand rotation	Left and right hand rotation
Materials:	Titanium, PEEK and Stainless Steel	PEEK and Stainless Steel	Titanium

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

Bench testing
In house design verification testing was performed to ensure that mechanical and functional requirements including design specifications were met. All tests completed met their pre-established acceptance criteria.

Test	Test Method Summary	Results
Ensuring the function between two service intervals for the ELAN 4 Electric Drill	Demonstrate functionality, performance characteristics and the safety of the product based on the intended use within service interval of one year.	Pass: All requirements met
Verification of the reactions times of the ELAN 4 Wireless Foot Control	Demonstrate the reaction time in the time between changing the logic level of the function and change in the button status byte	Pass: All requirements met

Biocompatibility
A biocompatibility evaluation was conducted according to International Standard ISO-10993, "Biological Evaluation of Medical Devices Part-1: Evaluation and Testing" and Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process", Guidance for Industry and Food and Drug Administration Staff, as appropriate for limited exposure (≤ 24 hours) externally communicating device with contact in the area of tissue/bone/dentin devices.

The materials of the Wireless Foot Control, Drill and Attachments are the same types of materials used in the predicate and reference device. There have been no material changes since the clearance of the ELAN 4 Electro Motor System (K152960) and Microspeed Uni Motor System (K053526).

Electrical safety and electromagnetic compatibility (EMC)
Electrical safety and EMC testing were conducted on the ELAN 4 Electro Motor System. The control unit, wireless foot control and drill were tested as part of the ELAN 4 Electro Motor System. The system complies with the IEC 60601-1 and UL 2601-1 standards for safety and the IEC 60601-1-2 standard for EMC.

Software Verification and Validation Testing
Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern, since a malfunction of latent design flaw in the software device could lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to minor Injury.

Animal and Clinical Testing
No animal or clinical testing was necessary for determination of substantial equivalence.

Conclusion
Based on the indications for use, design, materials, function, comparison to the predicate device, and performance testing performed, it can be concluded that the ELAN 4 Software V3.00, Wireless Foot Control, Drill and Attachments are substantially equivalent to the predicate, ELAN 4 Electro Motor System (K152960).