August 9, 2019

Aesculap, Inc.
Kathy A. Racosky
Sr. Regulatory Affairs Specialist
3773 Corporate Parkway
Center Valley, PA 18034

Re: K183203
Trade/Device Name: Aesculap ELAN 4 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: July 11, 2019
Received: November 19, 2018

Dear Ms. 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,

Matthew Krueger, M.S.E.
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K183203

Device Name
Aesculap ELAN 4 Tools

Indications for Use *(Describe)*

Aesculap ELAN 4 Tools are 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)

Aesculap ELAN 4 Tools
July 17, 2019

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@aesculapimplants.com

TRADE NAME: ELAN 4 Tools

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

SUBSTANTIAL EQUIVALENCE

The ELAN 4 Tools are substantially equivalent to the primary predicate, ELAN 4 Tools (K172709) and predicate Anspach Dissection Tools (K113476).

DEVICE DESCRIPTION

The ELAN 4 Tools are cutting devices designed for use with the ELAN 4 Electro Motor System. The ELAN 4 Tools are designed for cutting, sawing and drilling of bone. The ELAN 4 Tools have an attachment mechanism designed specifically for the type of motors and attachments with which they will be used. The ELAN 4 Tools are manufactured from stainless steel with some tools containing a coated layer of diamond chips. The ELAN 4 Tools are components of the ELAN 4 Electro Motor System (K152960).

INDICATIONS FOR USE

The ELAN 4 Tools are 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)

The ELAN 4 Tools are substantially equivalent to the predicate, ELAN 4 Tools (K172709) and the reference predicate Anspach Dissection Tools (K113476). The subject device is shown to be substantially equivalent and has the same performance characteristics to its primary predicate device through comparison in design, principles of operation and indications for use. The subject device has the same sizes and manufacturing materials as the reference predicate. A comparison table summarizing these characteristics can be found below.

The ELAN 4 Tools offer similar components when compared to the primary predicate, ELAN 4 Tools (K172709). The proposed device has some differences from the primary predicate device. The subject device ranges in sizes from 0.5 mm to 8 mm versus 0.6 mm to 9 mm for the predicate device. The subject device is manufactured from stainless steel with some tools containing a layer of diamond chips whereas the predicate is made from stainless steel. Similar to the devices that are subject to this submission, the predicate, Anspach Dissection Tool (K113476) are manufactured from the same materials; stainless steel with some tools containing a layer of diamond chips and range in the same sizes as the subject device offers.

	Aesculap Inc. ELAN 4 Tools	**Aesculap Inc. ELAN 4 Tools**	**Anspach Dissection Tool**
K#	Proposed device	K172709 - Primary	K113476
Indications	The ELAN Tools are intended for high speed cutting, sawing, and drilling of bone in the fields of Spine, ENT, Neuro, and Maxillofacial Surgery.	The ELAN Tools are intended for high speed cutting, sawing, and drilling of bone in the fields of Spine, ENT, Neuro, and Maxillofacial Surgery.	Dissection tools are intended for cutting and shaping bone including spine and cranium.
Regulation number	882.4310	882.4310	882.4310
Product Code	HBE	HBE	HBE
Regulatory Panel	Neurology	Neurology	Neurology
Tools			
Burrs & drills --Size	0.5 mm to 8 mm	0.6 mm to 9 mm	0.5 mm to 24.5 mm
--Type	fluted, ball, conical, oval, barrel, acorn, pin, twist, drills, cutters, and discs	fluted, ball, conical, oval, barrel, acorn, pin, twist, drills, cutters, and discs	fluted, ball, conical, oval, barrel, acorn, pin, twist, drills, cutters, and discs
Materials	Stainless steel & diamond	Stainless steel	Stainless steel, diamond, carbide
Attachment mechanism	Yes	Yes	Yes
Sterile Single Use	Yes	Yes	Yes
Sterilization	GAMMA irradiation	GAMMA irradiation	unknown

PERFORMANCE DATA

Biocompatibility Testing

Biocompatibility testing in accordance to ISO 10991-1 and Use of International Standard ISO 10993-1, "Biological evaluation of medical devices –l Part 1: Evaluation and testing within a risk management process", Guidance for Industry and Food and Drug Administration Staff has been performed to demonstrate that the ELAN 4 Tools are substantially equivalent to other predicate devices.

Biocompatibility testing within this submission includes the following: Cytotoxicity, Sensitization, Intracutaneous Irritation, Acute Systemic Toxicity, Hemolysis, and Pyrogen testing. In addition, endotoxin testing was conducted with all testing meeting the acceptance criterion.

Sterilization Validation

Product sterilization is validated in accordance with the ANSI/AAMI/ ISO 11137-1:2006 - Sterilization of health care products -- Radiation -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices and ISO 11137-2:2006 - Sterilization of health care products -- Radiation -- Part 2: Establishing the sterilization dose.

The ELAN 4 Tools are packaged and sterilized by gamma irradiation.

Packaging is validated per ISO 11607. Testing per ASTM F1980 validated the 5 year shelf life. Accelerated aging data (5 years) for ELAN 4 Tools has been generated to support this submission.

Bacterial Endotoxin testing per Endotoxin ISO 10993-5 met the acceptance criterion.

Bench Testing

The following bench testing was performed to demonstrate that the ELAN 4 Tools perform as intended and are substantially equivalent to the predicate devices.

Test	Test Summary	Results
Rotating performance test for rotating tools	Design suitable for speeds up to 80,000 rpm for 2 minutes	Pass
Measurement of temperature	With constant pressure and regular irrigation, evaluated bone temperature increase after milling, drilling or cutting	Pass

CONCLUSION:

The biocompatibility and bench testing results along with a comparison between the technology, materials and intended use for the ELAN 4 Tools and the predicate devices demonstrate that the ELAN 4 Tools are as safe, as effective, and perform as well as the predicate devices. The biocompatibility and bench testing results and technological comparison demonstrates that the ELAN 4 Tools are substantially equivalent to the predicate devices.