



January 19, 2019

Aesculap, Inc.  
Kathy Racosky  
Senior Regulatory Affairs Specialist  
3773 Corporate Parkway  
Center Valley, Pennsylvania 18034

Re: K182527

Trade/Device Name: 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: December 20, 2018  
Received: December 20, 2018

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/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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Matthew C. Krueger -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

## Indications for Use

510(k) Number (if known)  
K182527

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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

*Aesculap ELAN 4 Tools  
December 20, 2018*

**COMPANY:** Aesculap<sup>®</sup>, 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](mailto: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 predicate, Anspach Dissection Tools (K113476) and the reference device, Aesculap ELAN 4 Electro Motor System (K152960).

**DEVICE DESCRIPTION**

The ELAN 4 Tools are cutting devices designed solely for use with the ELAN 4 Electro Motor System. The ELAN 4 Electro Motor System 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 either a diamond coated or tungsten carbide head. The ELAN 4 Tools are components of the ELAN 4 Electro Motor System.

**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, Anspach Dissection Tools (K113476) and the reference device ELAN 4 Electro Motor System (K152960). 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, intended use, and materials. The subject device has the exact same indications as the reference predicate. A comparison table summarizing these characteristics can be found below.

The ELAN 4 Tools offers similar components when compared to the primary predicate, Anspach Dissection Tools (K113475). The only difference is the subject device ranges in sizes 0.6 mm to 25 mm versus 0.5 mm to 24.5 mm for the predicate device (K113475). Similar to the devices that are subject to this submission, the reference predicate, ELAN 4 Electro Motor System (K152960) also has the same indications for use.

|                             | <b>Aesculap Inc.<br/>ELAN 4 Tools</b>   | <b>Anspach Dissection Tool</b>  |
|-----------------------------|---|---|
| <b>K#</b>                   | Proposed device   | K113476 - Primary   |
| <b>Indications</b>          | 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. |
| <b>Regulation number</b>    | 882.4310  | 882.4310  |
| <b>Product Code</b>         | HBE   | HBE   |
| <b>Regulatory Panel</b>     | Neurology   | Neurology   |
| Burrs & drills              |   |   |
| --Size                      | 0.6 mm to 25 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      |
| <b>Materials</b>            | Stainless steel, diamond, tungsten carbide  | Stainless steel, diamond, carbide   |
| <b>Attachment mechanism</b> | Yes   | Yes   |
| <b>Sterile Single Use</b>   | Yes   | Yes   |
| <b>Sterilization</b>        | 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 –I 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.

A biological risk assessment was conducted in order to evaluate the overall biological safety of the ELAN 4 Tools. The results of this testing demonstrated that the ELAN 4 Tools are substantially equivalent to the predicate devices.

### **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 burrs and disc | Design not suitable, suitable for speeds up to 100,000 rpm  | 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.