DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 22, 2016

Aesculap, Inc.
Mr. Peter Stoll
Regulatory Affairs Specialist
3773 Corporate Parkway
Center Valley, PA 18034

Re: K152960
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: June 3, 2016
Received: June 23, 2016

Dear Mr. Stoll:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carlos L. Pena -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152960

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 Electro Motor System

July 21, 2016

COMPANY:	Aesculap®, Inc. 3773 Corporate Parkway Center Valley, PA 18034 Establishment Registration Number: 2916714
CONTACT:	Peter Stoll 610-984-9076 (phone) 610-791-6882 (fax)
TRADE NAME:	ELAN 4 Electro Motor System
COMMON NAME:	Drills, Burrs, Trephines & Accessories (Simple, Powered)
CLASSIFICATION NAME:	Powered simple cranial drills, burrs, trephines and their accessories
CLASSIFICATION PANEL:	Neurology
REGULATION NUMBER:	21 CFR 882.4310
PRODUCT CODE:	HBE

SUBSTANTIAL EQUIVALENCE

The ELAN 4 Electro Motor System is substantially equivalent to Aesculap's Microspeed Uni Motor System cleared via K053526.

DEVICE DESCRIPTION

The ELAN 4 Electro motor system is an electrical motor system consisting of a control unit with different sizes and types of handpieces, each containing its own integrated motor, and attachments such as burrs, saw blades, drills, etc. 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. System settings are controlled with the touch screen panel of the control unit, while all functions of the handpieces can be controlled from the sterile field by the foot control.

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.

TECHNOLOGICAL CHARACTERISTICS (compared to predicates)

The modifications made to the ELAN 4 Electro motor system do not affect the fundamental scientific technology. The design, materials, and principal of operation have not changed for these devices. The ELAN 4 Electro Motor System offers similar operating speeds, power sources, and attachments as the predicate device. A table of the modifications between the predicate and the ELAN 4 Electro is below. The performance of the device was determined to be equivalent or improved for the device, in comparison to the predicate, due to each of the changes. Material changes such as changing to stainless steel or another type of PEEK were evaluated and determined to

present no new risk to patients. Additionally, new features such as the distal tool adaptation and burr release mechanism were determined to present no new risk to patient and improved the performance of the device by reducing temperature and ensuring burrs do not release during use. This comparison supports the claim of substantial equivalence to the predicate device for the proposed intended use.

Comparison To Predicate

Device Modification	**Risk**	**Verification Activity**	**Acceptance Criteria**	**Results of Verification**
handpieces (GA)				
material change from titinium alloy to stainless steel	No new risk to patient.	Verification testing and biocompatibility testing per ISO 10993-1	Engineering specification	Pass. Does not raise new questions of safety and effectiveness.
material change from PEEK (blue) to PEEK (black)	No new risk to patient.	Verification testing (also see Appendix A below)	Engineering specification	Pass. Does not raise new questions of safety and effectiveness.
motor and handpiece has no coupling (one piece)	no new risk to patient	Verification testing (also see Appendix A below)	Engineering specification	Pass. Does not raise new questions of safety and effectiveness.
tool adaption at distal end of handpiece	no new risk to patient	Verification testing (also see Appendix A below)	Engineering specification	Pass. Does not raise new questions of safety and effectiveness.
burr release only in off position mechanism	no new risk to patient	Verification testing (also see Appendix A below)	Engineering specification	Pass. Does not raise new questions of safety and effectiveness.

System	**Elan 4 Electro (subject of this submission)**	**Microspeed Uni**
K#	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.	Aesculap's 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		
Maximum	80,000 rpm	80,000 rpm

speed		
Voltage	100-240 V	100 – 240V
Frequency	50-60Hz	50 – 60Hz
Irrigation Pump	Yes	Yes
Motor		
High speed motor Min/Max	10,000/ 80,000 rpm	5,000 rpm / 80,000 rpm
Low speed motor Min/Max	1,000/ 20,000 rpm	3,000 rpm / 40,000 rpm
Motor rotation High speed	Left and right hand rotation	Left and right hand rotation
Low speed	Left and right hand rotation	Left and right hand rotation
Materials	Stainless Steel	Titanium Alloy
Features		
Control mechanism	Foot	Hand and foot
Ability to connect various Handpieces	Yes	Yes
Motor connections	2	2
Footswitch connections	1	1
Control Unit	Touch screen	Touch screen
Applied standards	UL2601-1 IEC60601-1 IEC60601-1-2 IEC62304	UL2601-1 IEC60601-1 IEC60601-1-2

PERFORMANCE DATA

ELAN 4 Electro Motor System has been tested in accordance with FDA recognized standards IEC 60601-1, IEC 60601-1-2, IEC 62304, and UL 2601-1. Bench testing was performed with each handpiece to demonstrate equivalent or improved performance in comparison to the predicate device. Bench testing summaries are below. Each handpiece demonstrated equivalent or improved performance compared to the acceptance criteria.

Bench Testing of ELAN 4 Attachments

Elan 4 Bench Testing Handpieces Summary Table

Requirement	Acceptance	Sample	Results

contour milling could be performed without affecting the test pattern itself.	as representative of the standard tool portfolio "XS" is per application and processing cycle with the test pattern to be milled {Drill hand pieces GA861 and GA864} in bone replacement material {ash hardwood}. Definition of the tools used,	120 cycles	The 120 application cycles, i.e. "a" contour milling could be performed without affecting by the test pattern itself Pass
Coupling Toolfunctions	Tool is manually decouple d {with actuator)	120 times	120 times "OK", ie at 120 cycles of use, the tool was automatically coupled and uncoupled manually. There were no problems with tool coupling. PASS
Determining the weight before the RDG / after the RDG / after the oiling / after the Sterilization has shown that the weight remained constant before and just after the entire processing cycle.	No impairment of function and safety by cleaning, Disinfection and steam sterilization	120 cycles	During the preparation and application of 120 cycles, there were no function and safety impairments caused by cleaning, disinfection and steam sterilization. PASS
To evaluate the acceptance criteria, all analysis of all of the other 20 acceptance criteria can be used. Since all other 20 acceptance criteria were "satisfied" rated, this also applies to requirement (5). After and during 120 application and processing cycles, there was no functional and safety impairments.	No impairment of function and safety during and after at least 100 applications and processing cycles	120 cycles	Since all other acceptance criteria were satisfied this requirement can be determined to have met acceptance criteria. PASS

After 120th processing and application cycles all relevant information (manufacturer, part number, serial number) the labels are still identifiable / readable.	Labels are still readable after min.100 application and processing cycles	120 cycles	After 120 cycles all relevant information are still identifiable/readable. PASS
120 times "OK", at 120 cycles of use, the motor cables could be easily coupled and uncoupled.	Motor cable can be coupled and uncoupled	120 cycles	After 120 cycles the motor cables could be easily coupled/uncoupled. PASS
120 times "no", ie at 120 cycles of use, there was no interruption of operation through the cable	No interruption of operation by releasing the cable	120 cycles	After 120 cycles there was no interruption of operation through the cable. PASS
120 times "no", at 120 cycles of use, there was no operation interruption due to failure of electrical components.	interruption of operation due to failure of electrical components	120 cycles	After 120 cycles no operation interruption due to failure of electrical components. PASS
120 times "no", ie at 120 cycles of use, there was no interruption due to failure of mechanical components.	No interruption of operation due to failure of mechanical components	120 cycles	After 120 cycles no operation interruption due to failure of mechanical components. PASS
120 times "no", at 120 cycles of use the tool during application was securely locked and there was thus no interruption	Tool is securely locked during the function test and the use	120 cycles	After 120 cycles the tool was securely locked and there was no interruption. PASS

Temperature measurement: Check temperature of hand-piece at 3 defined times during the course of the 120 cycle test	After a certain number of cycles the duration test (def., "7 test procedure" ") a temperature measurement is performed. The temperature should be no higher than 48 ° C.	120 cycles	5th, 51st, and 101st cycle are all PASS

Elan 4 Bench Testing Craniotome Handpiece Summary Table

Requirement	Acceptance Criteria	Sample Size	Results
Tools can be attached automatically and released manually	Tool can be consistently coupled and uncoupled	123 cycles	After 123 cycles the tool was automatically coupled and manually decoupled with no problems. PASS
No performance or safety impairments were caused by cleaning, disinfecting or steam sterilization	Reprocessing procedure does not cause any functional or safety impairments	123 cycles	No performance or safety impairments caused by cleaning, disinfecting or sterilization. Weight remained constant

To evaluate the acceptance criteria, all analysis of all of the other acceptance criteria can be used. Since all other acceptance criteria were "satisfied" rated, this also applies to requirement (5). After and during 123 application and processing cycles, there was no functional and safety impairments.	All other testing requirements must be passed	123 cycles	Since all other acceptance criteria were satisfied this requirement can be determined to have met acceptance criteria. PASS
After 123rd processing and application cycles all relevant information (manufacturer, part number, serial number) the labels are still identifiable / readable.	Labels and other identifying information remains readable after set amount of reprocessing cycles	123 cycles	After 123 cycles all relevant information are still identifiable/readable. PASS
123 times 'OK' motor cable could be easily coupled and uncoupled	Motor cable consistently couples and uncouples	123 cycles	After 123 cycles motor cables are easily coupled/uncoupled. PASS

123 times ‘no’ at 123 cycles there was no interruption of operation due to release of cable	No safety or function impairments due to cable release	123 cycles	After 123 cycles there was no interruption of operation due to cable release. PASS
123 times ‘no’ at 123 cycles there was no interruption of operation due to failure of electrical components	No safety or function impairments due to failure of electrical components	123 cycles	After 123 cycles there was no interruption of operation due to failure of electrical components. PASS
123 times ‘no’ at 123 cycles there was no interruption of operation due to failure of mechanical components	No safety or function impairments due to failure of mechanical components	123 cycles	After 123 cycles there was no interruption of operation due to failure of mechanical components . PASS
123 times ‘no’ at 123 cycles the tool was securely locked and there was thus no interruption	No safety or function impairments due to failure or tool lock mechanism	123 cycles	After 123 cycles the tool was securely locked and there was no interruption. PASS

Temperature measurement: Check temperature of hand-piece at 3 defined times during the course of the 123 cycle test	Temperature remains in acceptable range throughout testing	123 cycles	10th, 51st, and 101st cycle are all PASS

Elan 4 Bench Testing Perforator Summary Table

Requirement	Acceptance Criteria	Sample Size	Results
Processing test (See below for sub-tests)			
Sterilization Test (Processing sub-test 1)	Reprocessing does not result in any functional or safety issues	100 cycles	PASS
Bracket System Test (Processing sub-test 2)	Motors held securely during processing	100 cycles	PASS
Function Test (Processing sub-test 3)	Tool securely locked and could be safely removed	100 cycles	PASS
Plug Testing (Processing sub-test 4)	Motor cable was safe, easy and error-free coupling and uncoupling	100 cycles	PASS
Lubrication Testing (Processing sub-test 5)	Lack of lubrication did not cause impairment of function or safety	100 cycles	PASS
Perforation Test	Perforator broke through material and turned off automatically after breaking through	100 cycles	PASS

Weight and Temperature Test	Perforator hand piece maintained a consistent weight and temperature range throughout testing	100 cycles	PASS

Elan 4 Bench Testing Reciprocating Saw Handpiece Summary Table

Requirement	Acceptance Criteria	Sample Size	Results
Cleaning and Disinfection Test	No functional or safety issues caused by cleaning and disinfection procedures	100 cycles	PASS
Sterilization Test	No functional or safety issues caused by sterilization procedure.	100 cycles	PASS
Bracket Test	Saw held securely during reprocessing, transport and storage	100 cycles	PASS
Lubrication Test	No impairment of safety or function due to lack of lubrication	100 cycles	PASS
Function Test	Tool is static and locked securely. Tool can be safely removed. Oscillation of tool functions. No functional or safety issues as a result of material changes	100 cycles	PASS
Motor Cable Test	Motor cable can be coupled and uncoupled safely, easily, and without error.	100 cycles	PASS
Performance Test	Sawing motion (oscillation) is consistent and cut is at least 6cm.	100 cycles	PASS
Temperature Measurement Test	Temperature remains in acceptable range throughout testing	100 cycles (temperature measured every 20 cycles)	PASS

Elan 4 Bench Testing Sagittal Saw Handpiece Summary Table

Requirement	Acceptance Criteria	Sample Size	Results
Cleaning Test	No function or safety issues as a result of the cleaning and disinfection procedure	100 cycles	PASS
Sterilization Test	No function or safety issues as a result of the sterilization procedure	100 cycles	PASS
Bracket Test	Saw remained secure during reprocessing, transport and	100 cycles	PASS
Lubrication Test	No safety or function issues due to lack of lubrication	100 cycles	PASS
Motor Cable Test	No impairment of the connection and disconnection process	100 cycles	PASS
Performance Test	Sawing motion and cut is constant and consistent	100 cycles	PASS
Temperature Test	Temperature remains in acceptable range throughout testing	100 cycles	PASS

SUBSTANTIAL EQUIVALENCE CONCLUSION

Bench testing results along with a comparison between the technology and materials used in the ELAN 4 Electro Motor System and the predicate device, demonstrates that the ELAN 4 Electro Motor System meets or exceeds the performance of the predicate device. Bench testing for each handpiece was conducted with pass/fail criteria that would demonstrate equivalent or improved performance in comparison to the predicate as intended in the specified use conditions. The bench testing results and technological comparison demonstrate that the ELAN 4 Electro Motor System performs comparably to the predicate device currently marketed.