April 11, 2021

adeor medical AG
Ulrike Winkler
Vice President QM/RA/R&D
Martinshof 5
Valley, Bavaria 83626
Germany

Re: K191479
Trade/Device Name: Velocity Alpha Highspeed Surgical Drill 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: March 8, 2021
Received: March 10, 2021

Dear Ulrike Winkler:

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,

Xiaolin Zheng -S

Xiaolin Zheng, Ph.D.
Director
DHT5A: Division of Neurosurgical,
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and Neurodiagnostic Devices
OHT5: Office of Neurological
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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)*
K191479

Device Name
Velocity Alpha Highspeed Surgical Drill System

Indications for Use *(Describe)*

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

I.	**Company:**	adeor medical AG Martinshof 5 83626 Valley Germany
II.	**Contact:**	Ulrike Winkler Vice President QM / RA / R&D (QMR)
III.	**Preparation Date:**	04th March, 2020
IV.	**Proprietary Trade Name:**	Velocity Alpha™ Highspeed Surgical Drill System
V.	**Common Name:**	Powered Drill System
VI.	**Classification Name:**	Drills, Burrs, Trephines & Accessories (21 CFR 882.4310)
VII.	**Classification:**	Class II
VIII.	**Product Code:**	HBE

IX. Market device claiming equivalence to:
The electric drill system is substantially equivalent to the Aesculap ELAN 4 Electro Motor System cleared via K152960.

X. Device Description:
The Velocity Alpha™ Highspeed Surgical Drill System is an electric AC powered surgical motor drill system for rapid cutting, sawing, drilling and manipulation of soft tissue and bone.

The Subject Device has several components, such as an electric motor hand piece connected to and driven by an AC-powered control unit, a foot control unit (wired or wireless (Bluetooth)) and several adapters and nosepiece attachments, e.g. straight & angled nosepiece attachments, craniotome attachments, speed reducer attachments and sawing attachments.

The device has an optional irrigation pump that can supply irrigation through sterile tubing. Speed is variable from 1.000 RPM up to 80.000 RPM in order to adjust the speed to the surgeon's requirements. The direction of rotation can be pre-selected to the left and to the right.

XI. Intended Use / Indications for Use:

The Velocity Alpha™ Drill System is indicated for trepanating, incision, cutting, removal, shaping, sawing of soft and hard tissue, bone, and bone replacement materials.

Applications:	Cutting, removing, shaping and sawing hard and soft tissue, bone, and bone replacement materials.
Areas of use:	Neurosurgery and spinal surgery.

XII. Comparison of the Technological Characteristics and Substantial Equivalence:

The technological characteristics of subject device are based on the same highspeed motor drill technology as the predicate devices.

Item	New device	Predicate device	Equiva-lence
Trade Name	Velocity Alpha™ Highspeed Surgical Drill System	Aesculap ELAN 4 Electro	-
Picture			-
Intended Use	The Velocity Alpha™ Drill System is indicated for trepanating, incision, cutting, removal, shaping, sawing of soft and hard tissue, bone, and bone replacement materials. Applications: Cutting, removing, shaping and sawing hard and soft tissue, bone, and bone replacement materials. Areas of use: Neurosurgery and spinal 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.	Similar
Control Unit			
Maximum speed	80,000 rpm	80,000 rpm	Identical
Voltage	100-240 V	110-240 V	Identical
Frequency	50-60 Hz	50-60 Hz	Identical
Irrigation Pump	Yes	Yes	Identical
Motor			
High speed motor (min / max)	1.000 / 80.000 rpm	10.000 / 80.000 rpm	Identical
Motor rotation	Right and left speed rotation	Right and left speed rotation	Identical
Materials	Stainless Steel	Stainless Steel	Identical
Foot Control			
Control buttons	4 buttons for • pump on/off • Forward/reverse	3 buttons: • Pump on/off • Forward/reverse	Substantially equivalent – no question to

	• Change programs • Motor control (on/off and variable)	• Foot pad	safety and effectiveness
Power supply:	• Wireless via 3xAA batteries • cable	Cable	Substantially equivalent – no question to safety and effectiveness
Features			
Control mechanism	Foot or touch screen	Foot or touch screen	Identical
Ability to connect different motor handpieces	no	yes	Identical
Motor connections	1	2	Identical
Footswitch connections	1	1	Identical
Control unit	Touch screen	Touch screen	Identical
Applied standards	IEC60601-1 IEC60601-1-2 IEC62304	IEC60601-1 IEC60601-1-2 IEC62304	Identical
Materials			
Control unit with housing	Plastic material	Plastic material	Identical
Motor with cable	Stainless steel	Stainless steel	Identical
attachments / nosepieces	Stainless steel	Stainless steel	Identical
Hygiene / Maintenance			
Cleaning	The foot control is water-tight according to IPX8, 1 m depth of immersion, 1 hour (water-tight in accordance with IEC 60529). Control Unit and foot control (cabled or Bluetooth): cleaning wiped with moist tissue. Wiping disinfection. Attachments: validated manual and mechanical cleaning and disinfection. For more details see IFU page 30 to 35). Cutters/burrs: only sterile packed single-use cutters/burrs are being used (not part of this submission, see HiCUT Instruments K130755).	Similar cleaning procedure. (see annex IFU ELAN4 Electric System)	Substantially equivalent – no question in safety and effectiveness
Sterilization	Gravity method: 15min, 132°C, drying time: 20min Pre-vacuum method: 4min, 132°C, drying time: 16min For more details see IFU page 35.	• Steam Autoclave/Gravity Air Displacement 132°C/ 15 minutes wrapped or unwrapped 30 minutes dry time • Steam autoclave / Pre-vacuum: 132°C/ 3 minutes wrapped or unwrapped, 30 minutes dry time.	Substantially equivalent – no question in safety and effectiveness

XIII. Substantial Equivalence Discussion:

The technologic characteristics of the subject device are based on the same electric motor drill technology as the predicate devices. The adeor® Velocity Alpha™ Highspeed Surgical

Drill System is substantially equivalent to the predicate devices based upon the comparison of the technological characteristics.
Any difference that exists between the Velocity Alpha™ Highspeed Surgical Drill System and the predicate devices has no negative effects on safety or effectiveness of the subject device when used as labelled.

XIV. Performance data testing:

Test	Description	Acceptance criteria	Results
Functional (motor speed / torque analysis)	Analyzed motor speed / torque curve	Torque was reached as specified	Pass
Temperature	Analyzed motor temperature during activity	Temperature was in compliance to specifications.	Pass
Lifetime	Analyzed System lifetime during regular duty cycle	The System functioned according to specifications.	Pass
Noise level	Analyzed Noise level during activity	The Noise level did not exceed the limit.	Pass
Electrical Safety	Electric powered instruments evaluated for electrical safety	Be aligned with IEC60601-1:2005 Electrical Safety	Pass
Electromagnetic Compatibility	Electric powered instruments evaluated for electromagnetic compatibility	Be aligned with IEC60601-1-2:2014 Electromagnetic compatibility	Pass

XV. Wireless Foot control:

For the wireless foot switch (VAFCBT) software verification/validation of the functions of the foot switch was conducted according to IEC 62304:2006. Additionally, EMC testing was performed to evaluate the risk of communication loss according to IEC 60601-1-2:2007 and Electrical Safety Tests have been done according to IEC 60601-1-1:2005.

XVI. Software:

Software validation meets the requirements according to IEC 62304:2006: Medical device software – Part 1: Guidance on the application of ISO 14972 to medical device software.

XVII. Biocompatibility:

Biocompatibility was evaluated on attachments/nosepieces which have patient contact and meets the requirements of ISO10993.
In addition, Biocompatibility testing per EN ISO 10993-1 was performed.

XVIII. Animal and Clinical Performance Data:

No clinical data is required for this device classification submission.

XIX. Conclusion:

Substantial equivalence of the adeor® Velocity Alpha™ Highspeed Surgical Drill System can be assumed based on the similarity of the devices' technological characteristics, functionality and indications of use.