March 6, 2026

Adeor Medical AG
Silvia Laube
Official Correspondent
Martinshof 5
Valley, BY 83626
Germany

Re: K253772
Trade/Device Name: Velocity Alpha® MR High Speed Surgical Drill System
Regulation Number: 21 CFR 882.4370
Regulation Name: Pneumatic Cranial Drill Motor
Regulatory Class: Class II
Product Code: HBB, HBE
Dated: February 5, 2026
Received: February 5, 2026

Dear Silvia Laube:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

JULIA E. SLOCOMB -S

Digitally signed by JULIA E. SLOCOMB -S
Date: 2026.03.06 08:28:51 -05'00'

for Jaime Raben, Ph.D.,
Division 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253772

Device Name
Velocity Alpha MR High Speed Surgical Drill System

Indications for Use *(Describe)*

The Velocity Alpha MR High Speed Surgical Drill System is indicated for trephination, incision, cutting, removal, shaping, sawing of soft and hard tissue, bone and biomaterials in or near a magnetic field of 3.0 Tesla or less for use in Neurosurgery

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:**	Dr. Silvia Laube Regulatory Affairs Manager Phone: +49 8024 477 17 43
III.	**Preparation Date:**	March 6th, 2026
IV.	**Proprietary Trade Name:**	Velocity Alpha MR High Speed Surgical Drill System
V.	**Common Name:**	Velocity Alpha MR High Speed Surgical Drill System
VI.	**Classification Name:**	21 CFR 882.4370 - Pneumatic cranial drill motor (Primary) 21 CFR 882.4310 - Powered simple cranial drills, burrs, trephines, and their accessories (Secondary)
VII.	**Classification:**	Class II
VIII.	**Product Code:**	HBB, HBE
IX.	**Primary Predicate Device:**	Stryker Aria Pneumatic System (K061725)

X. Device Description:

The Velocity Alpha MR High Speed Surgical Drill System is a pneumatic powered surgical motor drill system. The system supplies pressurized air to motor which powers rotary surgical instruments through the attachments. Rotational speed of the system is controlled by the foot pedal. The MR System consists of a motor, motor hose, two attachments, and 4 cutting instruments. Additionally, the system is compatible with the Velocity Alpha Pneumatic High Speed Surgical Drill System foot pedal and wall hoses. The Velocity Alpha MR High Speed Surgical Drill System, including both system-specific and system-compatible components, can be used in or near a magnetic field of 3.0 Tesla level or less.

XI. Indications for Use:

The Velocity Alpha MR High Speed Surgical Drill System is intended for trephination, incision, cutting, removal, shaping, and sawing of soft and hard tissue, bone and biomaterials in or near a magnetic field of 3.0 Tesla or less for use in Neurosurgery.

XII. Comparison of the Technological Characteristics and Substantial Equivalence:

Item	Predicate device	Subject device
Trade Name	The Stryker Aria Pneumatic System	Velocity Alpha MR High Speed Surgical Drill System
Manufacturer	Stryker Corporation	adeor medical AG
K#	K061725	K253772
Regulation	21 CFR 882.4370; Pneumatic cranial drill motor	21 CFR 882.4370; Pneumatic cranial drill motor 21 CFR 882.4310; Powered simple cranial drills, burrs, trephines, and their accessories
Product code	HBB	HBB, HBE
Class	II	II
Indications for Use	Not Publicly Available	Velocity Alpha MR High Speed Surgical Drill System is indicated for trephination, incision, cutting, removal, shaping, sawing of soft and hard tissue, bone and biomaterials in or near a magnetic field of 3.0 Tesla or less for use in Neurosurgery.
MR conditional	Not Publicly Available	Yes – up to 3.0 Tesla
Max. air pressure	Not Publicly Available	Max. operating pressure: 8 bar Min. operating pressure: 6 bar
Gas Type	Not Publicly Available	Compressed nitrogen or medical grade compressed air
Maximum speed	Not Publicly Available	80,000 rpm
Number of Cutting Instruments	Not Publicly Available	4

XIII. Substantial Equivalence Discussion:

The subject device Velocity Alpha MR High Speed Surgical Drill System is substantially equivalent to the predicate device Stryker Aria Pneumatic System with respect to intended use, technological characteristics, user handling, and key performance and safety characteristics. The subject device has been validated according to applicable biocompatibility, usability, and performance standards, demonstrating fulfilment of all performance and safety requirements. The Velocity Alpha MR High Speed Surgical Drill System does not raise any new questions of safety or effectiveness compared to the Stryker Aria Pneumatic System.

XIV. Performance Data Testing:

Validation & verification testing were conducted to support substantial equivalence to the predicate device.

Test	Test Method Summary	Results
Functional testing within MR suite	Cutting performance, motor speed, and system assembly, handling, and heating tested with 3.0 Tesla MRI	All tests fulfilled acceptance criteria. System functional performance is acceptable under simulated use conditions within intended use environment and therefore equivalent to predicate device.
Cadaveric drill testing	Drilling performance conducted under simulated use conditions using cadavers	Acceptance criteria were fulfilled. Drilling performance is acceptable for its intended use.
MR-conditional validation	Deflection tests of all system components and sub-components which may be disassembled conducted with 3.0 Telsa MRI. Testing conducted in accordance with the FDA guidance document "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment"	All acceptance criteria were met. Safety and efficacy equivalent to the predicate device.
Lifetime validation	Function and safety were assessed after expected lifetime duty cycles.	All tests fulfilled acceptance criteria. Function and safety were confirmed for the lifetime of the device and is therefore equivalent to predicate device.

Non-clinical performance testing was conducted, including:

functional validation, sterilization validation, cleaning validation (manual and automated), packaging validation, lifetime testing, MR-conditional testing, and biocompatibility testing. All testing met acceptance criteria and confirmed that the device performs as intended.

XV. Biocompatibility:

Biocompatibility testing of the subject device was conducted in accordance with the FDA biocompatibility guidance "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"". All relevant acceptance criteria were met for the device components categorized as external communicating devices in contact with neural tissue, bone and dentin for <24 hours.

XVI. Conclusion:

The subject device and the predicate device are equivalent in terms of intended use and technological characteristics. Both devices are pneumatically operated surgical drill systems intended for neurosurgical procedures in MR-conditional environments up to 3.0 Tesla. Performance testing, including functional validation, sterilization validation, cleaning validation (manual and automated), MR-conditional testing and biocompatibility evaluation have demonstrated that the design differences between the subject and predicate devices do not raise different questions of safety or effectiveness. Therefore, the Velocity Alpha MR High Speed Surgical Drill System is substantially equivalent to the legally marketed predicate device, the Stryker Aria Pneumatic System (K061725).