June 30, 2026

MeVis Medical Solutions AG
Anne Schmidt
Regulatory Affairs Manager
Caroline-Herschel-Str. 1
Bremen, 28359
Germany

Re: K260576
Trade/Device Name: MeVis AVM Contour
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: May 28, 2026
Received: May 28, 2026

Dear Anne Schmidt:

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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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,

Lora D. Weidner, Ph.D.
Assistant Director
Radiation Therapy Team
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260576

Please provide the device trade name(s).

MeVis AVM Contour

Please provide your Indications for Use below.

MeVis AVM Contour is intended for use by qualified medical professionals working in the field of neurosurgery or radiotherapy planning to manually create target contours for regions of interest in the cranial region through semi-automatic registration of 2D digital subtraction angiography (DSA) images onto 3D computed tomography (CT) scans.
The contours can be exported as DICOM RTStruct objects and are used in radiosurgery/-therapy treatment planning procedures to target specific brain regions.
The created contours are intended for further review, editing and approval by radiosurgery/-therapy planning specialists in third-party radiosurgery/-therapy treatment planning systems (not part of this submission).
The semi-automatic registration is restricted to/requires:
• X-ray, 2D DSA and 3D CT images of the brain
• X-ray images must be acquired in both frontal and sagittal direction

Intended Patient Population
MeVis AVM Contour is used for patients diagnosed with Arteriovenous Malformations (AVM) requiring stereotactic radiosurgery (SRS). These patients are adults, 18 years and older.

Intended User Profile
The intended users are qualified medical professionals, working in the field of neurosurgery or radiotherapy planning (Neurosurgeons and Radiation Oncologists).

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☐ Adults (22 years old and greater)

MeVis

510(k) Summary

K260576

1 Submitter

Submitted Name:	MeVis Medical Solutions AG Caroline-Herschel-Straße 1 28359 Bremen Germany
Establishment Name:	MeVis Medical Solutions AG
Establishment Registration Number:	3010601176
Date Prepared:	
Contact Person:	Anne Schmidt Manager Regulatory Affairs
Telephone:	+49 (0)421 22495-120
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2 Device

Device Trade Name:	MeVis AVM Contour
Regulation:	CFR 21 892.2050
Classification Name:	Medical image management and processing system
Product Code:	LLZ -system, image processing, radiological
Class:	Class 2

3 Predicate Device

510(k) Number	Predicate Device	Product Code
K212420	Brainlab Elements, Brainlab Elements Contouring, Brainlab Elements Fibertracking, Brainlab Elements Image Fusion, Brainlab Elements Image Fusion Angio	LLZ, JAK

4 Reference Device[1]

510(k) Number	Reference Device	Product Code
K190042	Brainlab Elements Image Fusion Angio 1.0	LLZ JAK, LHN

5 Device Description

The MeVis AVM Contour device is a specialized medical imaging software tool for DICOM CT, biplanar X-Ray and DSA images designed for qualified medical professionals working in the field of neurosurgery or radiotherapy planning.
The device integrates manual contouring tools, semi-automatic image registration, and ROI projection functions to support visualization, contouring, and export of 3D CT-based structures in DICOM RT Structure Set (RTStruct) format for subsequent treatment planning of arteriovenous malformation (AVM) diseases. The created contours are intended for further review, modification, and approval by radiosurgery or radiotherapy planning specialists using third-party treatment planning systems (not included in this submission).

6 Indications for Use

MeVis AVM Contour is intended for use by qualified medical professionals working in the field of neurosurgery or radiotherapy planning to manually create target contours for regions of interest in the cranial region through semi-automatic registration of 2D digital subtraction angiography (DSA) images onto 3D computed tomography (CT) scans.
The contours can be exported as DICOM RTStruct objects and are used in radiosurgery/-therapy treatment planning procedures to target specific brain regions.
The created contours are intended for further review, editing and approval by radiosurgery/-therapy planning specialists in third-party radiosurgery/-therapy treatment planning systems (not part of this submission).

The semi-automatic registration is restricted to/requires:

- X-ray, 2D DSA and 3D CT images of the brain
- X-ray images must be acquired in both frontal and sagittal direction

[1] In order to justify the acceptance criteria for the performance of the subject device's registration algorithm.

Intended Patient Population
MeVis AVM Contour is used for patients diagnosed with Arteriovenous Malformations (AVM) requiring stereotactic radiosurgery (SRS). These patients are adults, 18 years and older.

Intended User Profile
The intended users are qualified medical professionals, working in the field of neurosurgery or radiotherapy planning (Neurosurgeons and Radiation Oncologists).

7 Technological Characteristics Comparison

The technological characteristics of MeVis AVM Contour are similar to the identified legally marketed predicate device (see Table 2). The MeVis AVM Contour software uses fewer functionalities than the predicate device as it has a narrower indication. It only includes those functionalities necessary to fulfill its intended use.
Safety and effectiveness have been demonstrated by performance testing. Therefore, this difference in functionality is not substantial.

Table 1 Comparison table for indications for use.

Device	Indications for Use
Subject Device MeVis AVM Contour	MeVis AVM Contour is intended for use by qualified medical professionals working in the field of neurosurgery or radiotherapy planning to manually create target contours for regions of interest in the cranial region through semi-automatic registration of 2D digital subtraction angiography (DSA) images onto 3D computed tomography (CT) scans. The contours can be exported as DICOM RTStruct objects and are used in radiosurgery/-therapy treatment planning procedures to target specific brain regions. The created contours are intended for further review, editing and approval by radiosurgery/-therapy planning specialists in third-party radiosurgery/-therapy treatment planning systems (not part of this submission). The semi-automatic registration is restricted to/requires: • X-ray, 2D DSA and 3D CT images of the brain • X-ray images must be acquired in both frontal and sagittal direction Intended Patient Population MeVis AVM Contour is used for patients diagnosed with Arteriovenous Malformations (AVM) requiring stereotactic radiosurgery (SRS). These patients are adults, 18 years and older. Intended User Profile The intended users are qualified medical professionals, working in the field of neurosurgery or radiotherapy planning (Neurosurgeons and Radiation Oncologists).
Primary Predicate device: Brainlab Elements, Brainlab Elements Contouring, Brainlab Elements Fibertracking, Brainlab Elements Image Fusion, Brainlab Elements Image Fusion Angio (K212420)	Brainlab Elements Contouring provides an interface with tools and views to outline, refine, combine and manipulate structures in patient image data. The generated 3D structures are not intended to create physical replicas used for diagnostic purposes. The device itself does not have clinical indications. Brainlab Elements Fibertracking is an application for the processing and visualization of cranial white matter tracts based on Diffusion Tensor Imaging (DTI) data for use in treatment planning procedures. The device itself does not have clinical indications. Brainlab Elements Image Fusion is an application for the co-registration of image data within medical procedures by using rigid and deformable registration methods. It is intended to align anatomical structures between data sets. The device itself does not have clinical indications. Brainlab Elements Image Fusion Angio is a software application that is intended to be used for the co-registration of cerebrovascular image data. The device itself does not have clinical indications.

Table 2 Comparison table for Substantial Equivalence Discussion

Feature/ Item	MeVis AVM Contour **(subject device)**	**Predicate device**	**Comparison Result**
Device Name	**MeVis AVM Contour**	**Brainlab Elements, Brainlab Elements Contouring, Brainlab Elements Fibertracking, Brainlab Elements Image Fusion, Brainlab Elements Image Fusion Angio**	n/a
510(k) Number	n/a	K212420	n/a
Indications for Use	See Table 1	See Table 1	Substantially equivalent The MeVis AVM Contours indications for use covers a subset of indications of the predicate device. The MeVis AVM Contours indications for use refer to 2 out of 4 applications in Brainlab Elements: Brainlab Elements Contouring and Brainlab Elements Image Fusion Angios indications for use. The subject device is raising no new concerns regarding safety or effectiveness, as these are the only applications necessary to perform the intended use of MeVis AVM Contour.
Product Code	LLZ	LLZ, JAK	Same as the predicate device.
Intended Use	The MeVis AVM Contour device is a specialized medical imaging software tool designed for qualified medical professionals working in the field of neurosurgery or radiotherapy planning. It enables healthcare professionals to create manual 3D CT-based target contours for AVM as input for further radiosurgery/-therapy treatment planning.	Brainlab Elements is a medical device for processing of medical images, that is used to support treatment planning of surgical or radio-therapeutical procedures.	Substantially equivalent The MeVis AVM Contour intended use is a subset of the intended use of the predicate device. Both devices are used to process a variety of medical images in support of radiosurgery/-therapy planning.
Intended Users	The intended users are qualified medical professionals, working in the field of neurosurgery or radiotherapy planning (Neurosurgeons and Radiation Oncologists).	The intended users are medical professionals. Typical users as defined in the use case descriptions are: • Image Guided Surgery: Neurosurgeons, Ear-Nose-Throat (ENT) surgeons and Cranio- Maxillofacial (CMF) surgeons including their assistants • Radiotherapy: medical professionals who perform radiation treatment planning (medical physicists, radiation oncologists, dosimetrists, physicians, etc.)	Substantially equivalent The MeVis AVM Contouring intended users are a subset of the users for the predicate device. Both devices are intended for use by medical professionals.

Intended Patient Population	MeVis AVM Contour is used for patients diagnosed with Arteriovenous Malformations (AVM) requiring stereotactic radiosurgery (SRS).	In general, there are no demographic, regional or cultural limitations for patients. It is up to the user to decide if the system shall be used to assist a certain procedure.	Substantially equivalent This is a subset of the patients mentioned in the indications of the predicate device.
Environment of Use	MeVis AVM Contour is intended for use in clinical and hospital environments, particularly in radiotherapy planning departments and neurosurgical units. It is designed for flexible use, allowing it to run on standard PCs.	The device shall be used in a hospital office environment or rooms appropriate for surgical interventions or radiotherapy planning.	Substantially equivalent
Intended Part of the Body	cranial region	Spine, cranial region	Substantially equivalent MeVis AVM Contouring supports a subset of the regions that are supported in the predicate device.
Import of medical device image series	X-ray, 2D DSA and 3D CT images of the brain	2D DSA, 3D DSA, 3D CT, 3D MRA, DICOM support	Substantially equivalent MeVis AVM Contouring supports a subset of image series that are supported in the predicate device. X-ray images are a technical prerequisite for 2D-3D image registration and do not raise new concerns regarding safety and effectiveness.
Image registration	2D/3D	2D/3D, 3D/3D	Substantially equivalent MeVis AVM Contouring supports a subset of the image registration techniques that are supported in the predicate device.
Image segmentation of anatomical structures	manual	Manual, automated	Substantially equivalent MeVis AVM Contouring supports a subset of the image segmentation techniques/tools that are supported in the predicate device.

8 Performance Data

Non-clinical Tests Discussion:
MeVis AVM Contour is validated and verified against its requirements and intended use by the successful execution of the Validation and Verification Plan:

- Specifications have been tested to demonstrate the software performs as intended for its intended use according to IEC 62304 and ISO 14971.
- Usability tests have been performed to demonstrate that usability requirements are met.
- Security tests have been performed covering vulnerability scanning, penetration testing, and verification of implemented cybersecurity measures.
- Bench tests for semi-automatic image registration were performed to demonstrate that the product is substantially equivalent.

A summary of the software verification and validation activities is provided below:

Software verification and validation

Test	Objective	Acceptance Criteria	Method	Result
Unit Testing	Verify correct implementation of individual software components	Corresponding automated tests pass	Automated unit testing framework	Passed
Functional Testing	Verify correct implementation of system/software requirements	All system/software requirements are fulfilled; Pass/Fail criteria were based on the requirements	Functional test plan in simulated use environment	Passed
Acceptance Testing	Validate that user needs are fulfilled; Confirm the completeness of the implemented system requirements from an end-user perspective.	System operates as expected across all major areas; all system/software requirements are fulfilled; Pass/Fail criteria were based on the requirements and intended use	System test plan in simulated use environment, performed by subject matter experts	Passed

Usability Testing

Test	Objective	Acceptance Criteria	Method	Result
Usability Testing	Confirm safe and effective use	No critical use errors	Simulated use covering all tasks with representative users of intended user group	Passed
		Usability design principles are fulfilled	Heuristic evaluation (Nielsen usability heuristics) with in-house usability specialist	Passed
		High user acceptance	Qualitative assessment using a 5-point Likert score (system usability scale) with representative users of intended user group	Passed

Security Testing

Test	Objective	Acceptance Criteria	Method	Result
Security Testing	Verify correct implementation of security requirements and security controls	Security requirements are fulfilled	Security requirements test, vulnerability scanning/dynamic code analysis	Passed
Penetration Testing	Avoid exploitable vulnerabilities	No critical security issues	Grey-box test	Passed

Bench Testing

For the semi-automatic image registration validation tests were performed to demonstrate that the product is substantially equivalent:

- The objective accuracy of the automated image registration algorithm (without manual refinement by the user) was evaluated using phantom data and retrospective clinical routine data.
- The expected alignment accuracy was set as ≤1 mm.
- The datasets used are suitable for demonstrating the performance of the device is consistent with U.S. clinical use conditions, demographically and technically representative of typical clinical imaging conditions encountered in clinical stereotactic radiosurgery routine.
- The objectively achieved 3D-CT to 2D-DSA alignment accuracy is 0.44 mm (± 0.70 mm sd)

The accuracy testing confirms the device meets or exceeds the accuracy of 0.50 mm of the predicate device (K212420) and reference device (K190042).

Clinical Tests Discussion:

N/A - No clinical testing has been conducted to demonstrate substantial equivalence.

9 Conclusion

The 510(k) Pre-Market Notification for MeVis AVM Contour contains adequate information, data, and non-clinical test results to enable FDA – CDRH to determine substantial equivalence to the predicate device. MeVis Medical Solutions AG has determined that its device, MeVis AVM Contour, is substantially equivalent to the identified predicate device listed above.

Non-clinical performance testing has demonstrated that MeVis AVM Contour performs at least as safely and effectively as the predicate device in the context of its narrower indications for use.