September 4, 2025

Bayer Medical Care, Inc.
Purva Pandya
Sr. Global Regulatory Strategist
1 Bayer Drive
Indianola, Pennsylvania 15051

Re: K250893
Trade/Device Name: Ball Joint Guide Array (BJGA)
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: August 7, 2025
Received: August 7, 2025

Dear Purva Pandya:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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,

Jaime Raben -S

Jaime Raben, PhD
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)*
K250893

Device Name
Ball Joint Guide Array (BJGA)

Indications for Use *(Describe)*
The Ball Joint Guide Array (BJGA) is intended to assist with stereotactic guidance, placement, and fixation for the operation of surgical instruments or devices during the planning and operation of neurological procedures performed in conjunction with preoperative and perioperative MR imaging. These procedures include laser coagulation, biopsies, catheter placement, and electrode placement procedures.

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

Ball Joint Guide Array
Bayer Medical Care, Inc.

The Summary is prepared in conformance with 21CFR 807.92

1. SUBMITTER

Bayer Medical Care, Inc.
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Contact Person:
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Phone: +1 201-213-5042

Date Prepared: March 25, 2025

2. DEVICE

Name of Device:	Ball Joint Guide Array (BJGA)
Common or Trade Name:	Ball Joint Guide Array (BJGA)
Classification Name:	Stereotaxic Instrument
Classification Regulation:	882.4560 - Stereotaxic instrument
Regulatory Class:	II
Product Code:	HAW - Neurological Stereotaxic Instrument

3. PREDICATE DEVICE

Voyager Trajectory Array Guide (V-TAG, K180854).
This predicate is a Class II device regulated under 21 CFR 882.4560 - Stereotaxic instrument
This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

4. DEVICE DESCRIPTION

The Ball Joint Guide Array (BJGA) is a skull-mounted, single use stereotactic neurosurgical guidance device. It is manually operated and facilitates trajectory planning and guides instruments or devices to a specific location within the brain. The ball joint system can be used to support a wide range of

surgical trajectories into the brain. An image-guided neuronavigational system is used to register cranial landmarks and utilize presurgical neuroimaging data to align the BJGA with an optimal skull entry point to achieve the planned trajectory. Once aligned, the BJGA assembly is securely attached to the skull and locked in position to provide a stable instrument/device guide. Intraoperative magnetic resonance imaging (MRI) is then used to confirm intraoperative trajectory alignment with the planned trajectory and make additional trajectory adjustments, as needed, prior to insertion of the neurosurgical instrument, guided via the BJGA, into the brain.

5. INDICATIONS FOR USE

The Ball Joint Guide Array (BJGA) is intended to assist with stereotactic guidance, placement, and fixation for the operation of surgical instruments or devices during the planning and operation of neurological procedures performed in conjunction with preoperative and perioperative MR imaging. These procedures include laser coagulation, biopsies, catheter placement, and electrode placement procedures.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

A table comparing key features of the subject and predicate devices is provided below. The BJGA has equivalent technological characteristics and functionality and is intended for the same use as compared to the predicate device.

Table 1 – Device Characteristics Comparison

	Predicate Device (K180854): V-TAG	**Subject Device:** Ball Joint Guide Array (BJGA)
Intended Use / Indications for Use	The V-TAG is intended to assist with stereotactic guidance, placement, and fixation for the operation of surgical instruments or devices during the planning and operation of neurological procedures performed in conjunction with preoperative and perioperative MR imaging. These procedures include laser coagulation, biopsies, catheter placement and electrode placement procedures.	The BJGA is intended to assist with stereotactic guidance, placement, and fixation for the operation of surgical instruments or devices during the planning and operation of neurological procedures performed in conjunction with preoperative and perioperative MR imaging. These procedures include laser coagulation, biopsies, catheter placement, and electrode placement procedures.
Intended User	Neurosurgeon	Neurosurgeon
Use Location	MRI Suite and OR	MRI Suite and OR
Operating Principle	Stereotactic guiding & fixation	Stereotactic guiding & fixation
Design Principle	Ball and socket joint fixed to skull using 4 bone screws	Ball and socket joint fixed to skull using 4 bone screws
“Frameless” stereotaxy	Yes	Yes
MRI Compatible	Yes	Yes

Single use disposable	Yes	Yes
Sterilization	Provided sterile	Provided sterile
Placement Accuracy Specification	X, Y, Z errors ≤2mm and angular error of ≤2°	X, Y, Z errors ≤2mm and angular error of ≤2°
Instrument size compatibility	14 Ga and 16Ga	14Ga and 16Ga
Biocompatible	Yes per ISO-10993	Yes per ISO-10993

7. PERFORMANCE DATA

The following non-clinical performance data has been provided in support of the substantial equivalence determination.

A. Performance Testing

Device performance testing included verification of the Placement Accuracy, Instrument Compatibility, Multi-Lumen, Angular Range of Motion, MRI Compatibility, and Functional Testing. All testing passed and the demonstrated product performance met all prior established acceptance criteria.

B. Biocompatibility Testing

Biocompatibility testing was conducted on the patient contact components to verify that they meet the requirements of ISO 10993-1: 2018 and the following FDA's guidance on the Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" (FDA, 2023). All biocompatibility testing successfully passed.

C. Sterility, Packaging, and Shelf-Life Testing

The device is provided sterile and intended for single use only. Gamma radiation sterilization validation was conducted on the BJGA based on ISO 11137-1 and ISO 11137-2. The shelf-life of the device is labeled for 2 years based on accelerated aging testing. Packaging and simulated distribution testing was conducted on the final, finished device and passed successfully.

D. Human Factors Usability Validation Testing

Human factors and usability testing with the BJGA evaluated the functional and operational aspects of the device to demonstrate its safe and effective. Key elements evaluated include the operability of the device over procedural steps and comprehensibility of labeling materials.

8. CONCLUSION

The BJGA is substantially equivalent to the predicate device, V-TAG (K180854). This conclusion is based upon the devices having the same intended use and similar technological characteristics. While there are differences in design characteristics, these differences do not raise different questions of safety or effectiveness. The performance data demonstrate that the BJGA is as safe, as effective, and performs as well as or better than the predicate device.