June 4, 2025

Surgify Medical Oy
% Richard Lilly
Consultant
Avania, LLC
3031 Tisch Way, Suite 1010
San Jose, California 95128

Re: K251433
Trade/Device Name: Surgify Halo (54.085.SHD.H1); Surgify Halo (54.140.SHD.H1); Surgify Halo (54.070.NVG.H1); Surgify Halo (54.125.NVG.H1); Surgify Halo (54.000.SEE.H1); Surgify Halo (40.070.NVG.H1); Surgify Halo (40.125.NVG.H1); Surgify Halo (40.000.SEE.H1)
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: May 5, 2025
Received: May 8, 2025

Dear Richard Lilly:

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,

Adam D. Pierce -S

Digitally signed by Adam D. Pierce -S
Date: 2025.06.04 13:10:26 -04'00'

Adam D. Pierce, Ph.D.
Assistant 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)*
K251443

Device Name
Surgify Halo (54.085.SHD.H1); Surgify Halo (54.140.SHD.H1); Surgify Halo (54.070.NVG.H1); Surgify Halo (54.125.NVG.H1); Surgify Halo (54.000.SEE.H1); Surgify Halo (40.070.NVG.H1); Surgify Halo (40.125.NVG.H1); Surgify Halo (40.000.SEE.H1)

Indications for Use *(Describe)*
Surgify Halo is a sterile surgical burr indicated for shaping and removal of hard tissue and bone in Neurosurgical, Spinal, ENT, and General Surgical 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

This 510(k) Summary is submitted in accordance with the requirements of 21 CFR 807.87 and 807.92.

I. Submitter

Name:	Surgify Medical Oy
Address:	Otakaari 5 02150 Espoo, Finland
Phone:	+358 40 707 3200
Email:	jukka.kreander@surgifymedical.com
Contact Person:	Jukka Kreander, CQRO

Date Prepared:	May 28, 2025
Device Trade Name:	Surgify Halo
Device Common or Usual Name:	Burr
Regulation Name:	Powered simple cranial drills, burrs, trephines, and their accessories.
Regulation Number:	21CFR 882.4310
Product Code:	HBE
Device Class:	Class II
Classification Panel:	Neurology

II. Predicate Device

Predicate Name and 510(k) Number: Surgify Halo, K250380.

III. Device Description

The Surgify Halo is a sterile-packaged, single-use rotary cutting device (a burr) made from high-grade metallic materials, designed to cut bone and other hard tissues selectively while minimizing chattering. The device is similar to conventional surgical cutting burrs but includes a ring mechanism in the burr head to reduce chattering. Like traditional burrs, the device is designed to be compatible with commonly marketed, high-speed, surgical drill systems.

The Surgify Halo comprises:

- **Shank:** Transfers rotary motion from the drill motor to the burr head.
- **Locking Features:** Located at the distal end of the shank, these features securely attach the burr to the high-speed surgical drill.
- **Burr Head:** A head part, which is shaped to have both dual (5.4 mm) and single (4 mm) cutting edge configurations to cut hard tissue.
- **Safety Mechanism:** A self-centering ring and spring mechanism installed in the burr head. The moving ring, larger than the burr head, can adopt two positions:
    - **First Position:** (Hard Tissue Mode) The ring protrudes, preventing the cutting edges from engaging with the work material.
    - **Second Position:** (Soft Tissue Mode) The ring extends beyond the cutting edge, shielding it to minimize accidental soft tissues and an exposed position for cutting hard surfaces like bone.

IV. Indications for Use

Surgify Halo is a sterile surgical burr indicated for shaping and removal of hard tissue and bone in Neurosurgical, Spinal, ENT, and general surgical procedures.

V. Technological Characteristics

The technological characteristics of the subject Surgify Halo remain the same as the previously cleared device under K250380.

The similarities and differences do not alter the intended use of the device, nor do they affect the safety and effectiveness of the subject device relative to the predicate. Both the subject and predicate devices have the same intended use for shaping and removal of hard tissue and bone in Neurological, Spinal, ENT and general surgical procedures. The proposed modifications of adding new models for the optional burr size of 4mm is verified to ensure overall performance remains the same as the predicate with acceptable results.

In summary, the subject device has the following technological characteristics which are same as the predicate device:

1. **Intended use/Indications for Use:** The intended use/indications for use of the subject device are identical to those of the predicate device i.e. for shaping and removal of hard tissue and bone in Neurological, Spinal, ENT and general surgical procedures.
2. **Environment of Use:** The environment of use remains the same as the predicate, i.e., hospital use.
3. **Technology (Operating Principle):** The Surgify Halo Burr operates by transferring rotary motion from a high-speed surgical drill motor through the shank to the burr head. The burr head available in both dual and single cutting-edge configurations is designed for precise cutting and removal of

bone and hard tissue. A self-centering mechanism comprising a ring and spring ensures that the cutting edges only engage with the target tissue when appropriate, enhancing surgical precision and safety. The burr's position can be adjusted through the ring mechanism, which allows the burr to either prevent contact with the tissue or engage it, depending on the surgical requirements.

4. **Design Configuration:** The Surgify Halo Burr consists of a cylindrical shank with locking features at the distal end that securely attach the burr to the drill handpiece for stability. The burr head contains two precision cutting edges for efficient shaping and removal of bone and hard tissue. An end-attachment feature allows the Surgify Halo to be locked to commonly marketed high-speed surgical drill systems.
5. **Materials Compatibility:** Indirect tissue and bone contacting materials meet biocompatibility requirements.
6. **Compatible Interface:** The device is compatible with commonly available surgical drill handpieces and attachments, allowing for flexible integration into existing surgical setups.
7. **Sterility:** Single-use, Gamma Sterilization

VI. Performance Data

Performance testing requirements were determined through the application of a risk management process, applicable FDA guidance documents and performance standards (21 CFR §882.4310). Performance testing in support of substantial equivalence determination included:

- **Functional:** Testing (see table below) to verify that the device functions as intended, and all design and functional specifications are met for all models/system configurations. The relevant performance tests for the modified device included durability, chattering, and compatibility with drill systems.

Test	Test Method Summary	Results
Design Verification Tests	Device performance parameters. ▪ Durability ▪ Cutting Effectiveness ▪ Chatter Rate ▪ Noise ▪ Thermal	All tests fulfilled Design input requirements

- **Design Validation/Summative Evaluation:** The following design validation testing conducted supports a determination of substantial equivalence for the device .

  - Summative evaluation (see table below) was performed as part of the design validation activities to assess whether the user requirements were met, consistent with the evaluation approach used for the previous predicate device (K232684). . The usability assessments were conducted with production equivalent Surgify Halo (4 mm). This evaluation addressed the use errors and hazard related use scenarios from the risk analysis and was conducted in accordance with the requirements and principles of Human Factors and Risk Management outlined in IEC 62366-1:2015 and FDA's 2000 Guidance "Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management." (February 2016).

Test	Test Method Summary	Results
Design Validation and Summative Usability Testing	Surgeons Summative Testing: A series of tests based on hazard related use scenario, user interface (summative) evaluations to validate that the design meets intended use and user needs and to minimize user errors	All tests fulfilled Design input and user requirements

VII. Conclusions

The subject Surgify Halo device is substantially equivalent to the previously cleared predicate device (K250380).), as demonstrated by performance data and risk assessment. The intended use, technological characteristics and principle of operation are substantially equivalent to the predicate device. Thus, the subject Surgify Halo device is substantially equivalent to the predicate device.