



November 29, 2023

Surgify Medical Oy
% Sujith Shetty
Executive Vice President
Maxis Medical LLC
3031 Tisch Way Suite 1010
San Jose, California 95128

Re: K232684

Trade/Device Name: Surgify Halo
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: August 28, 2023
Received: September 1, 2023

Dear Sujith Shetty:

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.

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
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Enclosure

Indications for Use

510(k) Number (if known)

K232684

Device Name

Surgify Halo

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.

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510(k) Summary

This summary of 510(k) information is being submitted in accordance with the requirements of 21 CFR 807.92.

510 (k) number: K232684

Applicant Information

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Date Prepared: November 29, 2023

I Device Information

Trade Name: Surgify Halo

Common Name: Burr

Classification name: Powered simple cranial drills, burrs, trephines, and their accessories. (21CFR 882.4310)

Regulatory Class: Class II

Product Code: HBE

II Predicate Device**Table 1 Predicate Device**

Name	Manufacturer	510(k) #
Adeor HiCut Highspeed Instrument	ADEOR MEDICAL AG	K130755

No reference devices were used in this submission.

III Device Description

The Surgify Halo is a rotary cutting device made of high-grade metallic materials. It cuts bone and other hard tissues selectively while reducing chattering. The device is similar to conventional surgical cutting burrs with the addition of a ring mechanism installed in the burr head to reduce chattering. Similar to conventional burrs, the device is designed for use with compatible high-speed surgical drill systems.

The Surgify Halo comprises:

1. A shank, which transfers rotary movement of the drill motor to the head.
2. Locking features at the distal end of the shank which allow the burr shank to be locked to a high-speed surgical drill.
3. A head that is shaped to have two cutting edges to cut bone and hard tissue.
4. A safety mechanism consisting of a ring and spring installed in the burr head. The mechanism is self-centering and comprises a spring and a moving ring that is bigger than the burr head. The moving ring can have two different positions:
 - a. In the first position, the ring protrudes to a level higher than cutting edges and prevents the cutting edges from cutting into the work material.
 - b. In the second position, the ring retracts into the groove to a level lower than the cutting edges to allow the burr to cut the work material

Indications for Use

The 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.

IV Comparison of Technological Characteristics with the Predicate Device:

A comparison of the intended use, indication for use, and technological characteristics of the Surgify Halo to the predicate device has been performed. The attributes suggested in the FDA's website guidance for this comparison are provided in Table 2 and Table 3.

A. Intended Use

Table 2 *Intended Use*

	Subject Device Surgify Halo	Predicate Device Adeor HiCut Highspeed Instrument	Comment
Intended 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.	HiCut™ Highspeed Instruments are surgical burs indicated for trephination, incision, cutting, removal, shaping, sawing of soft and hard tissue, bone, and biomaterials in Orthopedic Surgery. Neurological and Spinal Surgery, ENT Surgery, Plastic and Maxillofacial Surgery, Arthroscopy, Sternotomy and General Surgery.	Substantially equivalent Surgify Halo has limited indications compared to the predicate device. The specific indications are a subset of indications already cleared for the predicate device.
21CFR Section	21 CFR 882.4310	21 CFR 882.4310	The same
Product Code	HBE	HBE	The same
Target Population	Adult	Adult	The same

	Subject Device Surgify Halo	Predicate Device Adeor HiCut Highspeed Instrument	Comment
Contraindications	The device contains nickel, and it should not be used on patients who are allergic or hypersensitive to medical-grade stainless steel or any of its alloying components.	None known	The same

B. Technological Characteristics

Table 3 Technology Characteristics

	Subject Device Surgify Halo	Predicate Device Adeor HiCut Highspeed Instrument	Comment
Type of operation	Open surgical procedures	Open surgical procedures	The same
Conditions for Use	Single use	Single use	The same
Sterilization	Supplied sterile, gamma irradiated	Supplied sterile, gamma irradiated	The same
Main Materials	Commonly used medical grade metals	Commonly used medical grade metals	The same
Packaging Configuration	A packaging system according to the requirements of ISO 11607 series of standards	A packaging system according to the requirements of ISO 11607 series of standards	The same

	Subject Device Surgify Halo	Predicate Device Adeor HiCut Highspeed Instrument	Comment
Available Style	Straight	Straight	The same
Driving motor	Compatible high-speed surgical drill systems	Compatible high-speed surgical drill systems	The same
Head Style Offering	Round	Multiple head styles available, including round , diamond, and pin	The same Both devices have a round head style available.
Diameter/Head Size	5.55 mm	1.0 mm-7.9 mm (round head style)	The same
Length	85 mm and 140 mm	5.9 cm, 6.1 cm, 8.2 cm, 11.25 cm, 12.6 cm, 19.0 cm, 26.65 cm	Similar Predicate lengths cover and include lengths of the Surgify Halo device
Max Speed	37,500 RPM	75,000 RPM	Similar There is no technical limitation for the predicate, as the device is attached to a compatible high-speed drill system where the RPM can be adjusted up to 75 000. The limitation of the Surgify Halo device rotational speed is based on the best performance of the Surgify Halo device.

V Performance Data:

Tests were performed on the Surgify Halo, which demonstrated that the device, performs comparably to and is substantially equivalent to the predicate device.

Tests included verification/validation testing to internal functional specifications. In addition, testing confirmed that the Surgify Halo device has an equivalent safety profile to the predicate device.

Therefore, the verification/validation testing conducted supports a determination of substantial equivalence for the device. In addition, evaluations and validations have been performed to demonstrate compliance to the applicable standards for biocompatibility.

A description of these non-clinical performance tests is included in **Table 4**

Table 4 Non-Clinical Performance Testing

Test	Test Method Summary	Results
Design Verification Test	Device performance parameters. • Durability • Cutter Efficiency • Chatter • Thermal • Noise • Metallic Contact The durability of the device if the device is used at higher speed (rpm) than recommended. Geometrical feature of the device that influences compatibility with the high-speed surgical drills. Geometrical feature of the device that influence blister design e.g., overall length and shaft diameter	All tests fulfilled Design input requirements
Noise Testing	Noise testing with suction and irrigation	All tests fulfilled Design input requirements

Test	Test Method Summary	Results
Design Validation Testing and Summative Usability Testing	Nurses Summative Testing- Series of tests based on hazard-related use scenario, user interface . 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 requirements
Performance Testing Animal	Comparisons of the performance of the Surgify Halo burr to conventional diamond and fluted burrs	The performance of the Surgify Halo burr was comparable to that of the conventional diamond and fluted burrs
Biocompatibility	Test plan was developed and executed in accordance with ISO 10993-1:2018 and ISO 14971:2007, relevant to the nature of body contact: • Externally communication device • Tissue/bone/dentin • Limited contact duration ($A \leq 24$ h)	Acceptable per ISO10993-01 (2018)
Sterilization and Shelf Life	Testing per VD _{max} Basic Evaluation, EN/ISO 11137-1/2 (2015)	Gamma irradiation method ensures effective conditions (Sterility Assurance level (SAL) < 10 ⁻⁶) to sterilize the product by application of a sterilization dose of 25 kGy.
Transportation Validation	Trasportaion testing per the standard ISTA 3A to confirm that the sterile barrier was maintained during simulated distribution	All tests fulfilled Design input requirements

VI Conclusions:

The Surgify Halo, based on the indications for use, product performance, and technological characteristics provided in this notification, has been shown to be substantially equivalent to the currently marketed predicate device. This 510(k) submission includes information on the Surgify Halo's technological characteristics, performance data, and verification and validation activities that demonstrate that the Surgify Halo is substantially equivalent to the predicate.