July 30, 2025

Tonica Elektronik A/S
% Freja Lüthje
Regulatory Affairs Specialist
MagVenture A/S
Lucernemarken 15
Farum, DK-3520
Denmark

Re: K252032
Trade/Device Name: T65 (9016E0611)
Regulation Number: 21 CFR 882.5805
Regulation Name: Repetitive Transcranial Magnetic Stimulation System
Regulatory Class: Class II
Product Code: OBP
Dated: June 30, 2025
Received: June 30, 2025

Dear Freja Lüthje:

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,

ROBERT KANG -S

for Pamela Scott
Assistant Director
DHT5B: Division of Neuromodulation and
Physical Medicine 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)*
K252032

Device Name
T65 (9016E0611)

Indications for Use *(Describe)*
Treatment of Major Depressive Disorder in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

Date Prepared: June 30, 2025

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DEVICE

Device Trade Name: T65

Classification Names: Repetitive transcranial magnetic stimulation system

Regulation: 21 CFR 882.5805
Regulatory Class: Class II
Device Panel: Neurology
Product Classification Code: OBP

PREDICATE DEVICE

Predicate Trade Name: Cool-B65
Predicate 510(k): K150641

DEVICE DESCRIPTION

The MagVenture Coil T65 is a figure-of-eight, actively cooled coil designed for use in transcranial magnetic stimulation (TMS) therapy as part of the MagVenture TMS Therapy System. The system delivers magnetic pulses for generating evoked responses, assessing motor thresholds (MT), and administering therapeutic treatments.
The T65 is a redesign of the treatment coil Cool-B65, to include the motor threshold (MT) determination capability of the C-B60 coil. This reduces the need for coil exchange during patient sessions, supporting a more streamlined workflow for clinicians.

The T65 incorporates several ergonomic and functional enhancements compared to the existing coil:

- Integrated intensity control wheel allowing direct manual adjustment of stimulation output.
- Built-in trigger button with LED status indication to display coil readiness.
- Reduced weight for improved maneuverability and ease of use.
- Strain relief mechanisms at both the coil and connector ends to improve durability and reduce cable stress.

INDICATIONS FOR USE STATEMENT

Treatment of Major Depressive Disorder in adult patients who fail to receive satisfactory improvement from prior antidepressant medication in the current episode.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The following table compares the T65 to the existing Cool-B65. The change does not affect the device's intended use and does not raise different questions of safety and effectiveness compared to the existing device.

Comparison of Technological Characteristics for New Device and Predicate Device

Element	**T65** Modified device	**Cool-B65** Predicate device	**Statement of equivalence**
Parts Number	9016E0611	9016E0491	N/A
Manufacturer	Tonica Elektronik A/S	Tonica Elektronik A/S	No difference
Coil picture			N/A
510(k) Number	K252032	K150641, K171481, K171967	N/A
Product code	OBP	OBP	No difference
Design	Figure-of-eight	Figure-of-eight	No difference
Condition of use	Used with a magnetic stimulator	Used with a magnetic stimulator	No difference
Weight of transducer head	1.42 kg	1.8 kg	Weight reduction; does not raise different questions of safety and effectiveness compared to the existing device.

Element	**T65** Modified device	**Cool-B65** Predicate device	**Statement of equivalence**
Trigger button in handle	Yes	Yes	No difference
Status LED	Integrated in trigger button	Besides trigger button	Formative testing in a standard-use scenario showed that LED position does not influence coil operation.
Intensity wheel	Yes	No	Functionally equivalent to C-B60 (K150641). Intensity control mechanism does not raise different questions of safety and effectiveness compared to the existing device. See Note-1 below.
Treatment protocols	Able to perform: MDD standard, 10 Hz 37 min. Cleared in K150641 MDD standard, 10 Hz 19 min. Cleared in K171481 MDD iTBS, 50 Hz 3 min. Cleared in K172667	Able to perform: MDD standard, 10 Hz 37 min. Cleared in K150641 MDD standard, 10 Hz 19 min. Cleared in K171481 MDD iTBS, 50 Hz 3 min. Cleared in K172667	No difference
Cooling	Active liquid cooling	Active liquid cooling	No difference
Intended purpose	Intended to apply a magnetic-field induced electrical current in the	Intended to apply a magnetic-field induced electrical current in the	No difference

Element	T65 Modified device	Cool-B65 Predicate device	Statement of equivalence
	body to activate neuronal structures.	body to activate neuronal structures.	
Indication for use	Treatment of Major Depressive Disorder in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode.	Treatment of Major Depressive Disorder in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode.	No difference
Target area	Left dorsolateral prefrontal cortex (L-DLPC)	Left dorsolateral prefrontal cortex (L-DLPC)	No difference
Intended use setting	Hospitals, Psychiatrist's office or clinic, Psychiatric hospitals, and general medical/surgical hospitals with psychiatric units.	Hospitals, Psychiatrist's office or clinic, Psychiatric hospitals, and general medical/surgical hospitals with psychiatric units.	No difference
Treatment population	Patients older than 18 years who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode.	Patients older than 18 years who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode.	No difference
Users	Treatment only performed by prescription and by or under the supervision of a licensed physician, introduced to the use of the	Treatment only performed by prescription and by or under the supervision of a licensed physician, introduced to the use of the	No difference

Element	T65 Modified device	Cool-B65 Predicate device	Statement of equivalence
	MagVenture TMS Therapy® and who have carefully read and understood the User Guide before performing any treatment.	MagVenture TMS Therapy® and who have carefully read and understood the User Guide before performing any treatment.	
Biocompatibility	Housing and handle: SABIC Lexan PC945-701	Housing: SABIC Lexan PC945-701 Handle: Röchling SUSTARIN-C POM	The T65 uses materials also used in Cool-B65; thus, no new materials are introduced. All materials are considered low risk per ISO 10993 and guidance from FDA [1]. No safety impact.
Electrical safety and EMC	Complies with IEC60601-1 and IEC60601-1-2	Complies with IEC60601-1 and IEC60601-1-2	No difference
Mechanical safety	Complies with IEC60601-1	Complies with IEC60601-1	No difference
Chemical Safety	Complies with IEC60601-1	Complies with IEC60601-1	No difference
Thermal safety	Complies with IEC60601-1	Complies with IEC60601-1	No difference
Quality & Risk standards	Complies with ISO 13485-2016 and ISO 14971:2019	Complies with ISO 13485-2016 and ISO 14971:2019	No difference

[2] Use of International Standards ISO 10993-1, "Biological evaluation of medical devices - Part 1: evaluation and testing within a risk management process" Sept. 8 – 2023 Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" | FDA

NON-CLINICAL TESTING AND PERFORMANCE STANDARDS

The T65 coil underwent comprehensive non-clinical testing to verify and validate its safety and performance in accordance with the FDA Guidance Document: "Class II Special Controls Guidance Document: Repetitive Transcranial Magnetic Stimulation (rTMS) Systems – Guidance for Industry and Food and Drug Administration Staff."

The T65 has been tested and conforms with the following recognized consensus standards:

- IEC 60601-1: General safety and essential performance requirements.
- IEC 60601-1-2: Electromagnetic compatibility compliance.
- ISO 13485:2016 & ISO 14971:2019: Quality and risk management compliance.

In addition, the T65 coil was tested to confirm that the magnetic field characteristics (e.g., pulse width, waveform, peak dB/dt) are within ±5% of the predicate Cool-B65 coil.

CLINICAL TESTING

No clinical testing is required to support this submission.

CONCLUSION

The T65 and the existing device have the same intended use and technological characteristics. The use of T65 does not raise any different questions regarding safety and effectiveness.