June 25, 2026

Longeviti Neuro Solutions
Brooke Lindsey
Program Manager
101 W. Dickman St., Suite 600
Baltimore, Maryland 21230

Re: K260709
Trade/Device Name: ClearFit Ti Ring 14mm (171750); ClearFit Ti Ring 14mm with Slot (171751); ClearFit Ti Ring 20mm (171752); ClearFit Ti Ring 20mm with Slot (171753); ClearFit Ti Ring 30mm (171754)
Regulation Number: 21 CFR 882.5330
Regulation Name: Preformed nonalterable cranioplasty plate
Regulatory Class: Class II
Product Code: GXN
Dated: May 26, 2026
Received: May 27, 2026

Dear Brooke Lindsey:

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,

JAIME RABEN -S

for Jaime Raben, Ph.D.,
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)*
K260709

Device Name
ClearFit Ti Ring 14mm (171750); ClearFit Ti Ring 14mm with Slot (171751); ClearFit Ti Ring 20mm (171752); ClearFit Ti Ring 20mm with Slot (171753); ClearFit Ti Ring 30mm (171754)

Indications for Use *(Describe)*
The Longeviti ClearFit(R) OTS cranial implants are manufactured to correct and/or restore bony voids and/or defects of the cranium.

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.

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510(k) Summary

Contact Details	
Applicant Name	Longeviti Neuro Solutions
Applicant Address	101 W. Dickman St., Suite 600 Baltimore MD 21230 United States
Applicant Contact Telephone	3046412212
Applicant Contact	Brooke Lindsey
Applicant Contact Email	blindsey@longeviti.com
Device Name	
Device Trade Name	ClearFit Ti Ring 14mm (171750); ClearFit Ti Ring 14mm with Slot (171751); ClearFit Ti Ring 20mm (171752); ClearFit Ti Ring 20mm with Slot (171753); ClearFit Ti Ring 30mm (171754)
Common Name	Preformed nonalterable cranioplasty plate
Classification Name	Plate, Cranioplasty, Preformed, Non-Alterable
Regulation Number	882.5330
Product Code(s)	GXN
Legally Marketed Predicate Device	
Predicate #	K231920
Predicate Trade Name	ClearFit OTS Cranial Implant
Product Code	GXN
Device Description Summary	
The Longeviti ClearFit OTS (off-the-shelf) cranial implants are ultrasound penetrable fixed size prosthetic cranioplasty plates intended to correct and/or restore bony voids and/or defects of the cranium. The implants are manufactured from polymethyl methacrylate materials with an integrated titanium alloy fixation ring. The devices are provided sterile and can be fixated to cranial bone using commercially available screws.	
Intended Use/Indications for Use	
The Longeviti ClearFit(R) OTS cranial implants are manufactured to correct and/or restore bony voids and/or defects of the cranium.	
Indications for Use Comparison	
The Longeviti ClearFit OTS cranial implants are manufactured to correct and/or restore bony voids and/or defects of the cranium. There are no changes to the Indications for Use for the ClearFit OTS cranial implants.	

Technological Comparison
The predicate ClearFit OTS cranial implant is manufactured from polymethyl methacrylate (PMMA) materials and is designed to be secured using PMMA fixation tabs with screws or with commercially available cranial fixation systems (e.g., plates and screws). The subject ClearFit OTS cranial implant has the same intended use and fundamental scientific technology as the predicate device. The subject device is manufactured from the same PMMA material using the same validated manufacturing process. The primary technological difference is the incorporation of an integrated titanium alloy fixation ring with fixation tabs, rather than PMMA fixation tabs. Titanium alloy is a well-characterized, biocompatible material commonly used in long-term implantable cranial fixation systems. The addition of the titanium fixation ring modifies the fixation method but does not alter the device's principle of operation or intended use. Verification and validation testing, including mechanical performance, biocompatibility, sterilization validation, and packaging validation, were conducted to evaluate the impact of the integrated titanium fixation ring. The results demonstrate that the technological differences do not adversely affect device performance and do not raise new questions of safety or effectiveness. Therefore, the subject device is substantially equivalent to the identified predicate device.
Non-Clinical and/or Clinical Tests Summary & Conclusions
Non-clinical performance testing was conducted to support a determination of substantial equivalence and to evaluate the impact of the integrated titanium fixation ring on device safety and performance. Testing included mechanical bench testing to assess fixation integrity and structural performance. Biocompatibility testing was conducted in accordance with ISO 10993-1 for a permanent implant with tissue and bone contact. Chemical characterization was conducted in accordance with ISO 10993-18, and a toxicological risk assessment was performed in accordance with ISO 10993-17. Sterilization validation was performed using vaporized hydrogen peroxide (VHP) in accordance with ISO 22441, to demonstrate achievement of a sterility assurance level (SAL) of 10^-6. Packaging validation was conducted in accordance with ISO 11607-1 and ISO 11607-2 to demonstrate package integrity and maintenance of sterility throughout distribution. Shelf-life evaluation, including environment preconditioning and accelerated aging, was performed in accordance with ASTM D4332 and ASTM F1980, respectively, to support the labeled expiration date. Seal strength and package integrity testing were performed in accordance with ASTM F88 and ASTM F2096. The results of these non-clinical tests demonstrate that the subject device performs as intended and that the technological differences do not raise new questions of safety or effectiveness compared to the predicate device. Clinical Testing: Not Applicable The results of nonclinical testing demonstrate that the subject ClearFit OTS Cranial Implant is as safe and as effective as the identified legally marketed predicate device and performs comparably under expected conditions of use. Mechanical bench testing conducted under worst-case conditions confirmed that the subject device provides adequate structural integrity and fixation performance. The incorporation of the integrated titanium fixation ring did not adversely affect device strength or functional performance relative to the predicate

configuration. Biocompatibility evaluation conducted in accordance with ISO 10993-1 for a permanent implant with tissue and bone contact demonstrated that the materials of construction are biocompatible and suitable for long-term implantation. Sterilization validation using vaporized hydrogen peroxide demonstrated achievement of a sterility assurance level (SAL) of 10^-6. Packaging validation and shelf-life testing confirmed that the device maintains package integrity and sterility throughout its labeled shelf life. No clinical testing was required to support substantial equivalence. Collectively, the nonclinical performance data support that the technological differences between the subject device and the predicate device do not raise new questions of safety or effectiveness, and the subject device is substantially equivalent to the predicate device.