September 8, 2021

Longeviti Neuro Solutions, LLC
Heather Hourihan, RAC
Director of Regulatory Affairs
303 International Circle Suite 190
Hunt Valley, Maryland 21030

Re: K212058
Trade/Device Name: Longeviti ClearFit OTS Cranial Implants
Regulation Number: 21 CFR 882.5330
Regulation Name: Preformed Nonalterable Cranioplasty Plate
Regulatory Class: Class II
Product Code: GXN, PJN
Dated: July 21, 2021
Received: August 5, 2021

Dear Heather Hourihan:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212058

Device Name
Longeviti ClearFit OTS Cranial Implants

Indications for Use *(Describe)*
The Longeviti ClearFit 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.

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LONGEVITI NEURO SOLUTIONS

510(k) Summary

Date Prepared:	September 8, 2021
Applicant:	Longeviti Neuro Solutions 303 International Circle Suite 190 Cockeysville, Maryland 21030 (410) 527-1803
Contact Person:	Heather Hourihan hhourihan@longeviti.com Director of Regulatory Affairs, RAC Longeviti Neuro Solutions

SUBJECT DEVICE

Trade Name:	Longeviti ClearFit™ OTS Cranial Implants
Common Name:	PMMA cranial implant
Class:	2
Classification:	882.5330
Procode:	GXN, PJN
Predicate Device:	Longeviti ClearFit™ Cranial Implant K202901
Device Description:	The Longeviti ClearFit™ OTS (off-the shelf) cranial implants are 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. The devices are provided sterile and can be fixated to cranial bone using commercially available fasteners.
Indication for Use:	The Longeviti ClearFit™ OTS Cranial Implants are manufactured to correct and/or restore bony voids and/or defects of the cranium.
Comparison of Technological Characteristics:	There are no significant technological differences between the Longeviti ClearFit™ Cranial Implant (K202901) and the Longeviti ClearFit™ OTS Cranial Implant. Longeviti manufactures ClearFit™ OTS Cranial Implants using the same raw materials and applying the same manufacturing processes used for their ClearFit™ Cranial Implant.

Tabular Comparison of Technological Characteristics:

Characteristics	**K212058 Longevity ClearFit ™ OTS Cranial Implant (Subject Device)**	**K202901 Longeviti ClearFit ™ Cranial Implant (Predicate Device)**	**Comments**
Device Classification	Class II	Class II	Same
Product Code	GXN, PJN	GXN, PJN	Same
Indications for Use	The Longeviti ClearFit ™ OTS Cranial Implants are manufactured to correct and/or restore bony voids and/or defects of the cranium.	The Longeviti ClearFit ™ Cranial Implant is designed and manufactured individually for each patient to correct bony voids and/or defects of the cranium.	Similar
Material	Polymethylmethacrylate (PMMA)	Polymethylmethacrylate (PMMA)	Same
Design	Fixed Size Implant	Patient Specific Implant	Different
Dimensions (cm^2)	$9cm^2$ - 37 cm^2	$25cm^2$ – $411cm^2$	Similar
Maximum thickness	5mm	5mm	Same
Radiopacity	Radiolucent	Radiolucent	Same
Sterilization	Ethylene Oxide	Ethylene Oxide (EO) or Vaporized Hydrogen Peroxide (VHP)	Similar
Biocompatibility	Implant device with permanent (>30 d) contact with tissue/bone	Implant device with permanent (>30 d) contact with tissue/bone	Same

Evaluations and Results to Support Substantial Equivalence:

Performance testing completed for the ClearFit™ (K202901) is applicable to the ClearFit™ OTS as Longeviti uses the manufacturing processes and materials validated for the ClearFit™ Cranial Implant to produce the ClearFit™ OTS Cranial Implant. Performance testing completed includes:

Method	Standard	Results
Tensile	ASTM D638-19: Standard Test Method for Tensile Properties of Plastics	Pass
Flexural	ASTM D790-15: Standard Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials	Pass
Impact	ASTM D4812-10: Standard Test Method for Unnotched Cantilever Beam Impact Resistance of Plastics	Pass

Conclusion:

Based on the similarities of the intended use/indications for use, technological and functional characteristics, and the results of the non-clinical performance testing, the ClearFit OTS cranial implant is substantially equivalent to the legally marked predicate device.