December 16, 2020

Longeviti Neuro Solutions, LLC
% Elaine Duncan
President
Paladin Medical, Inc
P.O. Box 560
Stillwater, Minnesota 55082

Re: K203349
Trade/Device Name: Longeviti ClearFit Cranial Implant
Regulation Number: 21 CFR 882.5330
Regulation Name: Preformed Nonalterable Cranioplasty Plate
Regulatory Class: Class II
Product Code: GXN, PJN
Dated: November 12, 2020
Received: November 13, 2020

Dear Elaine Duncan:

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)*
K203349

Device Name
Longeviti ClearFit™ cranial Implant

Indications for Use *(Describe)*
The Longeviti ClearFit™ cranial Implant is designed and manufactured individually for each adult patient to correct 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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510(k) Summary

Manufacturer	Longeviti Neuro Solutions, LLC 303 International Circle Suite 150 Hunt Valley, MD 21030
Contact Person	Name: Elaine Duncan, Paladin Medical, Inc. *regulatory consultant for Longeviti Neuro Solutions* P.O. Box 560, Stillwater, MN 55082 Phone: 715-549-6035 Email: duncan@paladinmedical.com
Date Prepared	December 16, 2020
Device Name	Trade Name: ClearFit™ Cranial Implant Common Name: Cranial Implant Classification Name: Plate, Cranioplasty, Preformed, Non-alterable
ProCode and Classification	Product Code: GXN, PJN Class II , 21CFR 882.5330
Predicate Device	K191210 - Longeviti ClearFit™ Cranial implant cleared under K191210.
Device Description	The Longeviti ClearFit Implant is patient specific, implantable prosthetic cranioplasty plates intended to correct and/or restore bony voids and/or defects of the cranium. The implant is manufactured from polymethyl methacrylate materials and are designed using the patient's CT scan data. The devices are provided sterile and can be fixated to cranial bone using commercially available fasteners. An identical backup implant may be supplied as a courtesy to the surgeon, according to custom, but is not required. The typical maximum single plate size does not exceed a total surface area of 411 cm2 and should have a nominal thickness of 4mm, not to exceed 5mm, to ensure physical integrity. Perfusion holes (also known as drainage holes) are available upon surgeon request at the time of ordering. Perfusion holes are 2mm in diameter and spaced at least 10mm apart.
Indication for Use	The Longeviti ClearFit implant is designed and manufactured individually for each adult patient to correct bony voids and/or defects of the cranium.

Performance Testing to Determine Substantial Equivalence	No new performance testing was required to determine substantial equivalence because the manufacturing and materials are identical to those described in K191210. The only additional testing for this submission was the addition of the acoustic property testing to support the labeling change. For this submission, acoustic properties were measured using time-delay spectrometry with a swept frequency (0.25-20MHz) ultrasound transducer, a hydrophone, and test samples mounted in an acoustic test tank. Continuous quality testing, including Gas Chromatography – Mass Spectrometry, is used to manage or confirm the absence of process drift which could potentially affect acoustic properties of the cast material.
Summary of Technological Similarities and Differences	There are no differences to the technology of the ClearFit in this submission and the predicate device of K191210. The predicate device did not include information or evaluation as to the acoustic properties of the ClearFit device. There are no technological differences to the biomaterial (PMMA) and no differences to the materials of manufacturing. There are no differences to packaging or sterilization processes. The only difference described in this Special 510(k) is the addition of descriptive parameters concerning the ultrasound attenuation of the ClearFit implant material to be included in the Instructions for Use (IFU).
Conclusion of Substantial Equivalence	The additional information to the ClearFit IFU regarding ultrasound attenuation does not change the indication for use or intended use of the ClearFit implant. The continuous quality testing confirms the ClearFit™ Cranial implant of this submission is substantially equivalent to the Longeviti ClearFit™ Cranial implant cleared under K191210.