January 9, 2020

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

Re: K191210
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: December 9, 2019
Received: December 10, 2019

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,

Matthew Krueger, M.S.E.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191210

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 Phone: (410) 527-1803
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 30, 2019
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
Substantially Equivalent To:	The Longeviti ClearFit™ Cranial implant is substantially equivalent to the following legally marketed devices: Longeviti PMMA Static Cranial Implant, Longeviti Neuro Solutions K170410
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 cm^2 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 Cranial implant is designed and manufactured individually for each adult patient to correct bony voids and/or defects of the cranium.
Comparison of Technological Characteristics	The changes compared to the Longeviti Cranial Implant covered in this submission are: 1) Trade name change and plural to singular description (previously updated via registration), 2) Recognition of option for perfusion holes and 3) description of process changes. There are no technological changes to the biomaterial (PMMA) and no change to the materials of manufacturing There are no changes to packaging or sterilization processes.
	Continued next page

These tests and their results contributed to the determination of Substantial Equivalence	**RESULTS- All assessments were found acceptable**
(ISO) 10993-1, (2018) Biological evaluation of medical devices -Part 1: Evaluation and testing within a risk management process (2018). ISO 10993-5 (2009), Biological evaluation of medical devices - Part 5: Tests for *in vitro* cytotoxicity. Material mediated pyrogenicity in the rabbit. conducted based on USP, General Chapter <151 >, Pyrogen Test. The procedure is recommended in ISO 10993-11, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity. Annex G: Information on material-mediated pyrogens (2017). ISO 10993-10, (2010) Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization. --- ISO Guinea Pig Maximization Sensitization Test and ISO Intracutaneous Study in Rabbits. Bioburden: AAMI 11737-1 methods Endotoxin pyrogenicity: ANSI ST72:2011/(R)2016 Glass Transition (Tg): ASTM D7028 Tensile strength: ASTM D638-14 Flexural strength: ASTM D790-15 Impact strength: ASTM D4812-11	
Conclusion:	The Longeviti ClearFit™ Cranial Implant is equivalent to the predicate, PMMA Static Cranial Implants, cleared under K170410, as shown by testing and qualification evaluations listed above.