March 23, 2018

Longeviti Neuro Solutions, LLC
% Elaine Duncan
President
Paladin Medical, Inc.
303 International Circle Suite T128
Hunt Valley, Maryland 21030

Re: K170410
Trade/Device Name: Longeviti PMMA Static Cranial Implant
Regulation Number: 21 CFR 882.5330
Regulation Name: Preformed Nonalterable Cranioplasty Plate
Regulatory Class: Class II
Product Code: GXN, PJN
Dated: February 15, 2018
Received: February 16, 2018

Dear Ms. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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)*
K170410

Device Name
Longeviti PMMA Static Cranial Implant

Indications for Use *(Describe)*
The Longeviti Static Cranial Implants are designed and manufactured individually for each 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Manufacturer	Longeviti Neuro Solutions, LLC 303 International Circle #T128 Hunt Valley, MD 21030
Contact Person	*Name*: Elaine Duncan, Paladin Medical, Inc. regulatory consultant for Longeviti Neuro Solutions *Phone*: 715-549-6035 *Email*: duncan@paladinmedical.com
Date Prepared	February 14, 2018
Device Name	*Trade Name*: Longeviti PMMA Static 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 PMMA Static Cranial Implant is substantially equivalent to the following legally marketed devices: Primary Predicate Device: OsteoSymbionics Patient Specific Cranial Plate (a.k.a. ClearSheild) – K133082 Secondary Predicate Device: OsteoSymbionics Patient Specific Cranial Implant – K072601
Device Description	The Longeviti PMMA Static Cranial Implants are patient specific, implantable 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 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. Typical maximum single plate sizes do 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.
Indication for Use	The Longeviti Static Cranial Implants are designed and manufactured individually for each patient to correct bony voids and/or defects of the cranium.

510(k) Summary

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<td>Summary of Testing and Basis for Substantial Equivalence</td>
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The Longeviti PMMA Static Cranial Implant are provided sterile. Sterilization validation was conducted according to the Overkill ISO-14937 approach 3 (conservative process definition based on inactivation of reference microorganisms) product challenge device method. The peracetic acid sterilization method conducted by contract sterilizer Revox Sterilization Solutions is the same method, cycle, and sterilizer as used by the primary predicate device manufacturer Osteosymbionics. (K133082)

The Longeviti PMMA Static Cranial Implant are fabricated from the same PMMA materials using the same methods as the Osteosymbionics Patient Specific Cranial Plate.

Longeviti contracted a certified and approved materials testing laboratory to perform a series of mechanical strength tests to demonstrate that the material is physically and mechanically substantially equivalent to the Osteosymbionics predicate material. The mechanical tests conducted were the following:
<table>
<tr><th>ASTM</th><th>Test Description</th></tr>
<tr><td>D638-03</td><td>Tensile properties of Plastics</td></tr>
<tr><td>D790-03</td><td>Flexural properties of unreinforced and reinforced plastics and electrical insulating materials</td></tr>
<tr><td>D4812-06</td><td>Unnotched cantilever beam impact</td></tr>
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Conclusion: The Longeviti PMMA Static Cranial Implants (design, materials, properties and indication for use) are substantially equivalent to predicate devices by Osteosymbionics; (K072601) and (K133082)
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