July 15, 2021

Longeviti Neuro Solutions, LLC
Heather Hourihan
Program Manager
303 International Circle Suite 190
Hunt Valley, Maryland 21030

Re: K211514
Trade/Device Name: Longeviti PorousFit implant
Regulation Number: 21 CFR 878.3500
Regulation Name: Polytetrafluoroethylene with Carbon Fibers Composite Implant Material
Regulatory Class: Class II
Product Code: KKY
Dated: May 14, 2021
Received: May 17, 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,

for Cindy Chowdhury, Ph.D., MBA
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control 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)*

K211514

Device Name

Longeviti PorousFit implant

Indications for Use *(Describe)*

Longeviti PorousFit implants are anatomical shapes intended for non-weight bearing augmentation and/or restoration of contour within the craniofacial skeleton.

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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Longeviti Neuro Solutions
Traditional 510k Submission- PorousFit Implants

510(k) Summary

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements under 21 CFR 807.92

Submitted By: 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

Date Submitted: July 13, 2021

Device Name and Classification:

Trade/Proprietary Name:	PorousFit implants
Common Name:	Porous HD Polyethylene (HDPE) implants
Classification Name:	Material, porous polymer, for maxillofacial reconstruction
Class:	II
Regulation:	21 CFR 878.3500
Procode:	KKY

Legally Marketed Predicate Devices:

Substantial Equivalent: OmniPore Surgical Implants (K123908)

Device Description:

Longeviti PorousFit implants are single-use, high density polyethylene (HDPE) for permanent implantation to restore the natural contour of the craniofacial skeleton. Devices are molded into various dimensions and shapes based on the area of the craniofacial skeleton requiring reconstruction and/or augmentation. PorousFit implants are provided sterile using ethylene oxide (EO).

Indication for Use:

Longeviti PorousFit implants are anatomical shapes intended for non-weight bearing augmentation and/or restoration of contour within the craniofacial skeleton.

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Longeviti Neuro Solutions
Traditional 510k Submission- PorousFit Implants

Similarities and Difference to the Predicate Device:

Similarities

Longeviti has contracted Matrix Surgical USA, owner of the OmniPore predicate device, to manufacture the PorousFit implants. The same raw materials, manufacturing processes, packaging materials, performance standards, and the same indication for use are used in the PorousFit implants and the predicate device.

Differences

There are no technological differences between the OmniPore Surgical Implants and the PorousFit implants.

Summary of Testing:

Testing completed by Matrix Surgical USA for their OmniPore implants are applicable to the Longeviti PorousFit implants. This includes biocompatibility evaluations (Cytotoxicity, ISO Systemic Toxicity, ISO Intracutaneous Study, USP Pyrogen Study, and ISO Muscle Implantation Study), mechanical evaluations, impact testing, purity testing per USP, and porosity testing.

Substantial Equivalence Conclusion:

Longeviti PorousFit implants will be manufactured by Matrix Surgical USA, owner, and manufacturer of OmniPore Surgical implants. There are no technological differences between PorousFit and OmniPore and Matrix will apply the same processes and materials used in manufacturing of OmniPore for the manufacturing of PorousFit. The processes and materials used for the manufacturing of the PorousFit implants are identical to the processes and materials used for the manufacturing of the OmniPore implants. For these reasons, the Longeviti PorousFit implants are substantially equivalent to the Matrix Surgical USA OmniPore surgical implants.