



November 21, 2024

LifeNet Health  
Brittany Beasley  
Sr. Manager, Global Regulatory Affairs  
1864 Concert Drive  
Virginia Beach, Virginia 23453

Re: K242799  
Trade/Device Name: PliaFX Flo  
Regulation Number: 21 CFR 888.3045  
Regulation Name: Resorbable Calcium Salt Bone Void Filler Device  
Regulatory Class: Class II  
Product Code: MBP, MQV  
Dated: September 16, 2024  
Received: September 17, 2024

Dear Brittany Beasley:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

JESSE MUIR-S

Digitally signed by JESSE  
MUIR-S  
Date: 2024.11.21 14:18:01  
-05'00'

Jesse Muir, Ph.D.  
Assistant Director  
DHT6C: Division of Restorative,  
Repair, and Trauma Devices  
OHT6: Office of Orthopedic Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K242799

Device Name

PliaFX® Flo

Indications for Use (Describe)

PliaFX® Flo is indicated for bony voids or gaps that are not intrinsic to the stability of the bony structure. It is indicated to be placed into the bony voids or gaps of the skeletal system (e.g., the extremities, spine and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. This product provides a bone void filler that remodels into the recipient's skeletal system.

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.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov)

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

## 510(k) Summary

### **Submitter Information:**

Company: LifeNet Health  
Address: 1864 Concert Drive  
Virginia Beach, Virginia 23453  
Contact: Brittany Beasley  
Sr. Manager, Global Regulatory Affairs  
Phone: (757) 609-4201  
Email: [brittany\\_beasley@lifenethealth.org](mailto:brittany_beasley@lifenethealth.org)  
Date Prepared: November 20, 2024

### **Device Information:**

Trade Name: PliaFX® Flo  
Common Name: Flowable Demineralized Fibers  
Regulation Number: 21 CFR 888.3045  
Regulation Name: Resorbable calcium salt bone void filler device  
Regulatory Class: Class II  
Product Code: MBP; MQV  
Proposed Panel: Orthopedic

### **Predicate Device:**

Name: K053098, Optium DBM

### **Device Description:**

PliaFX® Flo Flowable Demineralized Fibers is a sterile, freeze-dried, human bone allograft product consisting of demineralized bone matrix fibers combined with USP grade glycerol/glycerin. The subject device is pre-filled in a 3cc or 14cc delivery syringe based on product volume. The 3cc syringe configuration also includes an optional female luer cap.

### **Indications for Use:**

PliaFX® Flo is indicated for bony voids or gaps that are not intrinsic to the stability of the bony structure. It is indicated to be placed into the bony voids or gaps of the skeletal system (e.g., the extremities, spine and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. This product provides a bone void filler that remodels into the recipient's skeletal system.

### **Comparison of Technological Characteristics with the Predicate:**

The subject device is similar in materials, composition, packaging system configuration, and sterility to the predicate device. The differences in technological characteristics requiring 510(k) clearance include a change to the immediate container from a PETG jar to a pre-filled syringe,

minor differences in packaging, and a smaller product volume option. The biocompatibility and non-clinical performance testing included in this submission, including mechanical extrusion testing, leak testing, verification of plunger fit in barrel, and formative evaluation of extrusion force, unscrewing torque, and delivered volume, confirm that the proposed device does not raise different questions of safety or effectiveness.

**Conclusions:**

The submitted data demonstrates that the delivery syringe is capable of storing and delivering the bone void filler. Any differences between the subject device and the predicate device are minor and do not raise different questions concerning safety or effectiveness. Based on the indications for use, technological characteristics, and non-clinical data submitted, LifeNet Health has determined that the proposed device is substantially equivalent to the predicate device.