August 31, 2026

Global Life Sciences Solutions USA, LLC
Brian Goetz
Principal Regulatory Affairs Specialist – Medical
100 Results Way
Marlborough, Massachusetts 01752

Re: K261403
Trade/Device Name: Lipipor NLF1A Infusion Filter, Lipipor NLF2A & NLF2NTA Infusion Filters, Lipipor TNA2A Infusion Filter
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular administration set
Regulatory Class: Class II
Product Code: FPB
Dated: July 30, 2026
Received: July 30, 2026

Dear Brian Goetz:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

DAVID WOLLOSCHECK -S

David Wolloscheck, Ph.D.
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices, and
Human Factors
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K261403

Device Name
Lipipor NLF1A Infusion Filter
Lipipor NLF2A & NLF2NTA Infusion Filters
Lipipor TNA2A Infusion Filter

Indications for Use *(Describe)*

The Lipipor NLF1A, NLF2A, NLF2NTA, and TNA2A Infusion Filters are intended for use within the healthcare environment such as hospitals, healthcare facilities or clinical settings for infusion line filtering.
The Lipipor Infusion Filters are indicated for the removal of inadvertent particulate debris and microbial contaminants larger than 1.2 µm and entrained air which may be found in intravenous solutions, parenteral nutrition admixtures, and injectable lipid emulsions. They are also indicated for the removal of inadvertent enlarged lipid droplets from parenteral nutrition admixtures and injectable lipid emulsions.

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
PRAStaff@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."

K261403 - 510(k) SUMMARY
Global Life Sciences Solutions USA LLC
Lipipor NLF1A, NLF2A, NLF2NTA and TNA2A Infusion Filters

Submitter:	Global Life Sciences Solutions USA LLC
Address :	100 Results Way Marlborough, MA 01752
Primary Contact:	Nicky Wheatly Director, Medical Regulatory Affairs Global Life Sciences Solutions Operations UK Ltd 5 Harbourgate Business Park, Southampton Road Portsmouth PO6 4BQ United Kingdom of Great Britain Telephone Number: +442392338481 Email: nicky.wheatley@cytiva.com
Date Prepared:	31 Aug 2026
Trade Names:	Lipipor NLF1A Infusion Filter Lipipor NLF2A & NLF2NTA Infusion Filters Lipipor TNA2A Infusion Filter
Common Name:	Filter, Infusion Line
Classification Regulation:	21 C.F.R. § 880.5440, Intravascular administration set
Regulatory Class:	Class II
FDA Product Code:	FPB
Predicate Device:	Pall Corporation 3N1 Filter (K905794)

Intended Use / Indications for Use

The Lipipor NLF1A, NLF2A, NLF2NTA, and TNA2A Infusion Filters are intended for use within the healthcare environment such as hospitals, healthcare facilities or clinical settings for infusion line filtering.

The Lipipor Infusion Filters are indicated for the removal of inadvertent particulate debris and microbial contaminants larger than 1.2 µm and entrained air which may be found in intravenous solutions, parenteral nutrition admixtures, and injectable lipid emulsions. They are also indicated for the removal of inadvertent enlarged lipid droplets from parenteral nutrition admixtures and injectable lipid emulsions.

Device Description

The Lipipor NLF1A and TNA2A Infusion Filters are available in one model each. The Lipipor NLF2A Infusion Filter is available in two models, one for use when additional tubing from the filter to the patient is preferred (NLF2A), and the other for use when the additional extension tubing is not needed (NLF2NTA). All of the subject filters are disposable filters for infusion solutions that are comprised of the following components, with minor variations as outlined below:

- Filter housing - holds the filtering elements comprised of a 1.2 µm Supor (Polyethersulfone) hydrophilic membrane and Polytetrafluorethylene/polyester air elimination membrane.
  - In the NLF2A variant, the NLF2A filter housing has microbore tubing at the exit or downstream

port and a molded input port that permits connection using a female luer connector; the NLF2NTA filter housing has a male luer connector at the exit or downstream port and a molded input port that permits connection using a female luer connector.

- Female luer connector - provides connection to the tubing that is connected to the packaging that holds the infusion solution.
- Microbore tubing - one section of tubing connects the filter housing to the male luer connector and retains the tubing clamp; the other connects the female luer connector to the filter housing.
- Tubing clamp - provides a method to stop the flow of the infusion solution to the patient;
  - The NLF2NTA Infusion Filter is not supplied with microbore tubing or a tubing clamp.
- Male luer connector - provides connection to the medical device in contact with the patient.

Comparison of Technological Characteristics with the Predicate Device

The subject and predicate devices have the same fundamental design, consisting of the filter media and housing along with associated connection tubing/hardware. In addition, the subject and predicate filters operate based on the principle of size exclusion, also known as direct interception filtration, where particles larger than the pore size of the filter's hydrophilic membrane (1.2 µm) are retained and do not proceed with the solution to the patient.

The main technological differences between the subject Lipipor Infusion Filters and the predicate device are:

- The device housing sizes and effective filtration areas;
- The holdup volumes (resulting from the differences in filter housing sizes);
- The membrane material is polyethersulfone, versus polyamide (nylon) in the predicate;
- The maximum operating pressures are higher in the subject filters.
- A table comparing the key features of the subject and predicate devices is provided below.

	Subject Devices			**Predicate Device**	**Comparison**
Element	**NLF1A Infusion Filter**	**NLF2A & NLF2NTA Infusion Filters**	**TNA2A Infusion Filter**	**3N1 (TNA1) Intralipid filter (K905794)**	
Indications for Use	The Lipipor NLF1A, NLF2A, NLF2NTA, and TNA2A Infusion Filters are intended for use within the healthcare environment such as hospitals, healthcare facilities or clinical settings for infusion line filtering. The Lipipor Infusion Filters are indicated for the removal of inadvertent particulate debris and microbial contaminants larger than1.2 µm and entrained air which may be found in intravenous solutions, parenteral nutrition admixtures, and injectable lipid emulsions. They are also indicated for the removal of inadvertent enlarged lipid droplets from parenteral nutrition admixtures and injectable lipid emulsions.			This intralipid filter is indicated for use with any I.V administration set for the removal of microorganisms (*Candida albicans*), particulates (greater than 0.65 micron) and entrained air from total nutrient admixtures.	Different, supported by verification and validation testing. See note below table.
Filter Media	Polyethersulfone (Supor)			Polyamide (nylon)	Different, supported by

					biocompatibility testing
Air Elimination Membrane	Polytetrafluoroethylene (PTFE) / Polyester - hydrophobic; 0.03 µm rating			PTFE / Polyester – hydrophobic; 0.03 µm rating	Different, supported by air elimination testing
Typical Maximum Lipid handling / pumped infusion rate	10 mL/hr for 24 hrs for 20% lipid-emulsion (pumped at 10 mL/hr) & 50 mL/hr for 24 hrs for lipid containing admixture (pumped @ 50 mL/hr)	10 mL/hr for 24 hrs for 20% lipid-emulsion (pumped at 10 mL/hr) & 75 mL/hr for 24 hrs for lipid containing admixture (pumped @ 75 mL/hr)	100mL/hr for 5 hrs for 20% lipid-emulsion (pumped at 100 mL/hr) & 500 mL/hr for 6 hrs for lipid containing admixture (pumped @ 500 mL/hr)	300 mL/hr for 6 hrs for lipid containing admixture (pumped @ 300 ml/hr)	Different, supported by lipid handling tests
Lipid handling 1 meter gravity flow	N/A	N/A	100 mL/hr for >5 hrs for lipid containing admixture	N/A	Different, performance with gravity flow for TNA2A determined via bench testing
Water flow rate average 1m gravity flow	18 mL/min	24 mL/min (NLF2A) 79 mL/min (NLF2NTA)	150 mL/min	24 mL/min	Different, SE supported via bench testing
Typical Hold-up Volume	0.8 ml	1.2 ml (NLF2A) 1.0 ml (NLF2NTA)	12 ml	2.6 ml	Different, Hold up volume was determined via bench testing
Maximum operating pressure	30 psi/ 2 bar/ 1500mmHg				Same
Filtration Rating	1.2 µm	1.2 µm	1.2 µm	0.65 µm	Different, supported by microbial retention testing
Effective Filtration Area (cm^2)	1.65	4.5	18	11	Different, supported by testing confirming equivalent performance for the intended use
Air Elimination	Yes	Yes	Yes	Yes	Same, per air elimination/ venting testing

Filter Life (hrs.)	24	24	24	24	Same, supported by performance testing over 24 hour period
Shelf Life (yrs.)	5	5	3	5	Different, supported by shelf life testing

Note: The differences in labeling does not change the intended use, fundamental scientific technology, route of administration, patient population, or operating principles of the device. The text for the subject devices IFUs clarify and expand the description of established filtration functions rather than introduce new clinical claims. Verification and/or validation data support the stated filtration performance of the subject devices and the differences in labeling do not raise new questions of safety and effectiveness.

Performance Data

The following non-clinical testing was performed in support of the subject Lipipor Infusion Filters.

- *Sterilization Validation* in accordance with ISO 11137-1, ISO11137-2 and 11137-3 to ensure a minimum Sterility Assurance Level (SAL) of 10^{-6}
- *Biocompatibility* testing demonstrating conformance to ISO 10993-1 and FDA's corresponding June 2020 guidance document

Biological Endpoint testing	Standard
Cytotoxicity	ISO 10993-5 :2009
Sensitization	ISO 10993-10: 2010
Irritation	ISO 10993-10 :2010
Hemocompatibility	ISO 10993-4:2017
Acute Systemic Toxicity	ISO 10993-11: 2017
Subchronic Toxicity	ISO 10993-11:2017
Material Mediated Pyrogenicity	ISO 10993-11:2017

- *Bench top* testing : The following non-clinical (bench) testing, including standardized filtration efficiency tests, was conducted to demonstrate the subject devices' performance:

  Hold-Up Volume/ Bubble Point
  Burst Pressure / Water Flow Rate Lipid Handling
  Microbial Retention
  Leakage
  Air Venting / non-Leakage with Water

Air Venting with Lipid
Tensile Testing
Particulate Contamination
Chemical Requirements Testing
Slide Clamp Operational Testing
Visual inspection / Physical test for caps / Air Water Visual Interface
Lipid Droplet Size

Conclusion

The Lipipor NLF1A, NLF2A & NLF2NTA, and TNA2A Infusion Filters have the same intended use and similar indications for use, technological characteristics, and principles of operation as their predicate device, the Pall® 3N1 (TNA1) lntralipid Filter (K905794). The minor differences in indications do not alter the intended therapeutic use, nor do they affect the subject devices' safety and effectiveness when used as labeled. In addition, the minor technological differences between the devices raise no new questions of safety or effectiveness. Performance data further support that the subject devices are as safe and as effective as the predicate. Thus, the subject filters are substantially equivalent to the previously cleared predicate device.