



January 16, 2026

Medtronic
Makella Daley
Senior Regulatory Affairs Specialist
8200 Coral Sea St NE
Mounds View, Minnesota 55112

Re: K251744

Trade/Device Name: Affinity Pixie™ Arterial Filter with Balance™ Biosurface; Affinity® Pediatric
Arterial Blood Filter

Regulation Number: 21 CFR 870.4260

Regulation Name: Cardiopulmonary bypass arterial line blood filter

Regulatory Class: Class II

Product Code: DTM

Dated: June 6, 2025

Received: December 15, 2025

Dear Makella Daley:

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Nicole M. Gillette -S

Nicole Gillette

Assistant Director

DHT2B: Division of Circulatory Support, Structural, and
Vascular Devices

OHT2: Office of Cardiovascular Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K251744

Device Name

Affinity® Pediatric Arterial Blood Filter

Indications for Use (Describe)

The Affinity® Pediatric Arterial Blood Filter is indicated for use in cardiopulmonary bypass procedures up to 6 hours in duration for the removal of particulate and gaseous microemboli.

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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Indications for Use

510(k) Number (if known)
K251744

Device Name
Affinity Pixie™ Arterial Filter with Balance™ Biosurface

Indications for Use (Describe)

The Affinity Pixie™ Pediatric Arterial Filter is indicated for use in cardiopulmonary bypass procedures up to 6 hours in duration for the removal of particulate and gaseous microemboli.

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)

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13.0 510(k) Summary

Date Prepared: JUN 6, 2025

Submitter: Medtronic, Inc.
Medtronic Perfusion Systems
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Establishment Registration Number: 2184009

Contact Person: Makella Daley
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Device Name

| | |
|-------------|---|
| Trade Name | Affinity Pixie™ Arterial Filter with Balance™ Biosurface Affinity® Pediatric Arterial Blood Filter |
| Common Name | Cardiopulmonary bypass arterial line blood filter |

Device Class

| | |
|----------------------|-----------------|
| Classification | II |
| Regulation Number | 21 CFR 870.4260 |
| Classification Panel | Cardiovascular |
| Product Code | DTM |

Predicate Device Information

| Model | Description | Primary Predicate 510(k) |
|-------------------------------------|---|--------------------------|
| BB4014 | Affinity Pixie™ Arterial Filter with Balance™ Biosurface | K100646 |
| M942233A001 (non-sterile BB4014) | Affinity Pixie™ Arterial Filter with Balance™ Biosurface, non-sterile | |
| S4014 | Affinity® Pediatric Arterial Blood Filter | K071253 |
| M929334A001 (non-sterile S4014) | Affinity® Pediatric Arterial Blood Filter, non-sterile | |

K171979 is a reference for the non-sterile configurations of BB4014 (M942233A001) and S4014 (M929334A001) as they are used in Tubing Packs under K171979.

Device Description

The Affinity Pixie™ Arterial Filter with Balance™ Biosurface and Affinity® Pediatric Arterial Blood Filter are single-use, sterile, nonpyrogenic devices designed to filter microemboli greater than the specified micron size, from the circuit for periods up to six (6) hours, during cardiopulmonary bypass surgery. The Affinity Pixie™ Arterial Filter with Balance™ Biosurface device is coated with a non-leaching biocompatible surface to enhance blood compatibility and provide thromboresistant blood-contacting surfaces. The Affinity® Pediatric Arterial Blood Filter is uncoated. The models listed above will be referred to as Affinity Pixie™ Arterial Filter throughout the submission.

Principles of Operation

During Cardiopulmonary Bypass surgery, blood enters the arterial filter via a 1/4” barbed connection. Blood flows into the inlet chamber, where it circulates through a concentric folded screen before exiting the filter via a 1/4” outlet port located at the bottom of the support element.

The funnel shape of the inlet chamber prevents hemolysis and directs the blood flow through the filter.

Balance Coating

The polymer (Balance Biosurface) coating is applied to the device to enhance blood compatibility and provide thromboresistant blood-contacting surfaces.

Indications for Use

The Affinity Pixie™ Pediatric Arterial Filter is indicated for use in cardiopulmonary bypass procedures up to 6 hours in duration for the removal of particulate and gaseous microemboli.

The Affinity® Pediatric Arterial Blood Filter is indicated for use in cardiopulmonary bypass procedures up to 6 hours in duration for the removal of particulate and gaseous microemboli.

Description of Change

The purpose of this special 510(k) submission is to notify FDA of a change to the polyethylene film material used in the cone filter component (M926032A001 – Cone,

Pediatric arterial filter). This cone filter has direct, circulating blood contact and is used to remove particulate emboli from the bloodstream.

This change was notified to Medtronic by the cone filter supplier Sefar. The polyethylene film material is used to seal the two layers of the cone filter together. The polyethylene film has been discontinued and is being replaced with another polyethylene material.

Comparison to Predicate Devices

The modified Affinity Pixie™ Arterial Filter (which includes the subject cone filter component built with a new polyethylene film) have the following similarities to the predicate device which previously received FDA clearance per K100646 and K071253.

- Same intended use/indications for all devices in scope
- Same finished device operating principles for all devices in scope
- Same shelf life for all devices in scope
- Do not require clinical data to verify safety and efficacy
- Did not alter the sterilization process or reduce the sterilization requirements

When compared to the predicate device, the modified Affinity Pixie™ Arterial Filter (which includes the subject cone filter component built with a new polyethylene film) presented in this submission have the following material differences:

| Materials within Cone Filter component | Current material | Proposed material |
|---|--|--|
| Film | Chevron HD 9640 HDPE | Formolene E927ND HDPE |
| Filter | Medical grade 07-30/21 MEDIFAB polyester | Medical grade 07-30/21 MEDIFAB polyester |

In summary, based upon the examination of the comparison with the predicate devices, and the information presented in this submission demonstrates that the modified Affinity Pixie™ Arterial Filter (which includes the subject cone filter component built with a new polyethylene film) is substantially equivalent to the legally marketed predicate device.

Summary of Testing

Biocompatibility testing has been performed to support evaluation of the cone filter component (P/N M926032A001) used in the Affinity Pixie™ Arterial Filter after a material change in accordance with ISO 10993 and FDA Guidance Document on Use of 10993-1, “Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process”. The Affinity Pixie™ Arterial Filter with the new high density polyethylene formulation satisfies all biological endpoints with passing results and is therefore considered biocompatible for its intended use.

| Biological Endpoint / Extraction Condition | Result |
|--|---------------|
| ISO MEM Elution Cytotoxicity / 1x MEM with 5% serum, 2% antibiotics, and 1% L-glutamine at 37°C for 24hrs | Pass |
| Guinea Pig Maximization Sensitization / Normal Saline and Sesame Oil at 50°C for 72hrs | Pass |
| Intracutaneous Reactivity / Normal Saline and Sesame Oil at 50°C for 72hrs | Pass |
| Acute Systemic Toxicity / Normal Saline and Sesame Oil at 50°C for 72hrs | Pass |
| Material-mediated Pyrogenicity / Sterile, non-pyrogenic normal saline at 50°C for 72hrs | Pass |
| Hemolysis (extract and direct) / Calcium and Magnesium Free Phosphate Buffered Saline (CMF-PBS) at 50°C for 72hrs (extract) and at 37C for 3hrs (direct) | Pass |
| ASTM Partial Thromboplastin Time (PTT) with Comparison Article / Human Plasma at 37°C for 15 min | Pass |
| Platelet and Leukocyte Count assay with Comparison Article / Pooled Whole Human Blood at 37°C for 60min | Pass* |
| Complement Activation SC5b-9 assay with Comparison Article / Normal Human Serum at 37°C for 60min | Pass |
| Bacterial Reverse Mutation Assay / Polyethylene glycol and normal saline at 50°C for 72hrs | Pass |
| Mouse Lymphoma Assay / RPMI at 37°C for 72hrs and PEG at 50°C for 72hrs | Pass |

*See Attachment 12 for more details.

A separate design assessment and material property testing were conducted which concluded that the change has no impact on the final product functionality or performance.

Conclusion

In conclusion, the information included in this submission demonstrates that the modified Affinity Pixie™ Arterial Filter (which includes the subject cone filter component built with a new polyethylene film) is substantially equivalent to the legally marketed predicate device.