October 27, 2026

Teleflex Medical, LLC
Steph Pahl
Principal Regulatory Affairs Specialist
3015 Carrington Mill Blvd.
Morrisville, North Carolina 27560

Re: K262531
Trade/Device Name: OnControl Powered Bone Access Systems;OnControl Bone Marrow Aspiration System;OnControl Bone Marrow Biopsy System;OnControl Bone Lesion Biopsy System;OnControl Power Driver
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: Class II
Product Code: KNW
Dated: July 22, 2026
Received: July 22, 2026

Dear Steph Pahl:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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,

JESSICA CARR -S

Jessica Carr, PhD
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and
Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K262531

Please provide the device trade name(s).

OnControl Powered Bone Access Systems;
OnControl Bone Marrow Aspiration System;
OnControl Bone Marrow Biopsy System;
OnControl Bone Lesion Biopsy System;
OnControl Power Driver

Please provide your Indications for Use below.

The Arrow OnControl Bone Marrow Aspiration System is intended for bone marrow aspiration of the iliac crest of adult and pediatric patients age 2 and older.

The Arrow OnControl Bone Marrow Biopsy System is intended for bone marrow aspiration and core biopsy of the anterior or posterior iliac crest of adult patients.

The Arrow OnControl Bone Lesion Biopsy System is intended for bone biopsy of the vertebral body and bone lesions.

Please select the types of uses.	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☒ Children (2 years old to < 12 years old) ☒ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) Summary

[As required by 21 CFR 807.92]

Date Prepared: October 26, 2026

510(k) Number: K262531

Submitter's Name / Contact Person

Manufacturer
Teleflex Medical LLC
3015 Carrington Mill Blvd.
Morrisville, NC 27560

Contact Person
Steph Pahl
Principal Regulatory Affairs Specialist
Tel: 763.656.4276

Establishment Registration # 3011137372

General Information

Trade Name	OnControl Powered Bone Access Systems OnControl Bone Marrow Aspiration System OnControl Bone Marrow Biopsy System OnControl Bone Lesion Biopsy System OnControl Power Driver
Common / Usual Name	Instrument, Biopsy
Classification Name	21 CFR 876.1075, KNW, Gastroenterology-urology biopsy instrument, Class II
Predicate Device	K142377, The OnControl Bone Marrow Biopsy System by Vidacare
Reference Device(s)	K070759, Powered EZ-IO Pediatric Bone Marrow Aspiration System K113872, The OnControl Bone Access and Bone Biopsy System by Vidacare

Device Description

The OnControl Powered Bone Access Systems consists of the following devices:

- Bone Marrow Aspiration Needle Sets and Kits
- Bone Marrow Biopsy Needle Sets and Kits
- Bone Lesion Biopsy Kits
- OnControl Connectors
- OnControl Power Driver

The OnControl Powered Bone Access Systems are intended for aspiration, bone marrow biopsy, bone and bone lesion biopsy using a cutting (coring) technique by a trained clinician using image guidance systems (if required) in the vertebral body, iliac crest and/or bone lesions for the capture of bone, bone lesion(s), bone marrow or aspiration samples.

Indications for Use

The Arrow OnControl Bone Marrow Aspiration System is intended for bone marrow aspiration of the iliac crest of adult and pediatric patients age 2 and older.

The Arrow OnControl Bone Marrow Biopsy System is intended for bone marrow aspiration and core biopsy of the anterior or posterior iliac crest of adult patients.

The Arrow OnControl Bone Lesion Biopsy System is intended for bone biopsy of the vertebral body and bone lesions.

Comparison of Technological Characteristics with the Predicate Device

The subject device and predicate device have the same intended use and the indications for use for the subject device fall within the cleared indications for use of the predicate device. The key technological differences between the subject device and predicate device are the addition of components and sizes to the needle sets and kits, packaging modifications, modifications to the printed circuit board and firmware, and updates to performance specifications.

Substantial Equivalence and Summary of Studies

The technological differences between the subject and predicate devices have been evaluated through performance and biocompatibility tests to provide evidence of substantial equivalence for the OnControl Powered Bone Access Systems.

Device performance was verified through the following tests:

- Driver Functionality
- Structural Integrity
- Needle Set Functionality
- ISO 80369 Hub Verification

Device samples passed the following biocompatibility tests performed in accordance with ISO 10993-1:

- Cytotoxicity
- Sensitization
- Irritation
- Systemic Toxicity
- Material Mediated Pyrogenicity

Conclusion

The subject and predicate devices share the same intended use and fundamental scientific technology, including principle of operation. Differences in technological characteristics between the subject and predicate devices do not raise new or different questions of safety and effectiveness as demonstrated by bench tests. Therefore, the OnControl Powered Access Systems are substantially equivalent to the predicate device.