August 16, 2024

OnPoint Surgical, Inc.
Amy O'Donnell
Sr. Director Quality and Regulatory Affairs
555 Virginia Rd, Suite 103
Concord, Massachusetts 01742

Re: K241870
Trade/Device Name: OnPoint Augmented Reality Spine System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: SBF
Dated: August 14, 2024
Received: August 14, 2024

Dear Amy O'Donnell:

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.

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,

Shumaya Ali -S

Shumaya Ali, M.P.H.
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

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)*
K241870

Device Name
OnPoint Augmented Reality Spine System

Indications for Use *(Describe)*
The OnPoint Augmented Reality Spine System, with OnPoint Augmented Reality Spine System Software, is intended as an aid for precisely locating anatomic structures in either open or percutaneous spine procedures. The use of the OnPoint Augmented Reality Spine System is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a bony anatomical structure, such as the spine or pelvis, can be identified relative to CT images of the anatomy. This can include spinal implant procedures, such as pedicle screw placement, where the surgeon wants to see a tracked instrument location in relationship to the stereotaxic display of the CT images of the anatomy.

The optical head mounted display of the OnPoint Augmented Reality Spine System displays 2D stereotaxic screens and an optional virtual anatomy screen, paired with optional graphical targeting tools and alphanumeric displays. The stereotaxic screen is indicated for correlating the tracked instrument location to the registered patient images. The virtual screen is indicated for displaying the virtual instrument location in relation to the virtual anatomy to assist in percutaneous visualization and trajectory planning. The graphical targeting tools and alphanumeric display are indicated for providing visual and quantitative tracking information of the tracked instrument location including deviation from plan.

The virtual display should not be relied upon solely for absolute positional information and should always be used in conjunction with the displayed stereotaxic information.

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.***

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510(k) #: K241870

# 510(k) Summary

Prepared on: 2024-08-19

## Contact Details

21 CFR 807.92(a)(1)

| | |
|---|---|
| Applicant Name | OnPoint Surgical, Inc. |
| Applicant Address | 555 Virginia Rd Suite 103 Concord MA 01742 United States |
| Applicant Contact Telephone | 585-880-0356 |
| Applicant Contact | Ms. Amy O'Donnell |
| Applicant Contact Email | amy.odonnell@onpointsurgical.com |

## Device Name

21 CFR 807.92(a)(2)

| | |
|---|---|
| Device Trade Name | OnPoint Augmented Reality Spine System |
| Common Name | Stereotaxic instrument |
| Classification Name | Orthopedic Augmented Reality |
| Regulation Number | 882.4560 |
| Product Code(s) | SBF |

## Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

| Predicate # | Predicate Trade Name (Primary Predicate is listed first) | Product Code |
|---|---|---|
| K231284 | OnPoint Augmented Reality Spine System | OLO |

## Device Description Summary

21 CFR 807.92(a)(4)

The OnPoint Augmented Reality Spine System is intended as an aid for precisely locating anatomic structures in either open or percutaneous spine procedures. Infrared tracking technology is used to track the patient's anatomy as well as surgical instrumentation. The tracking information is registered with image information of the patient's anatomy in a common coordinate system. To guide the surgeon through the pedicle screw placement process, the system will display a visual representation of the following elements in an augmented reality optical head mounted display in addition to being displayed on a workstation monitor:

- Target position and orientation of the instrument path
- Current position and orientation of the instrument
- Cross sectional images
- 3D model of the patient's spine

Depending on surgeon preference, different combinations of these elements can be displayed. Optional planning steps allow the surgeon to define the target position and orientation as well as the length and diameter of the pedicle screws.

## Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The OnPoint Augmented Reality Spine System, with OnPoint Augmented Reality Spine System Software, is intended as an aid for precisely locating anatomic structures in either open or percutaneous spine procedures. The use of the OnPoint Augmented Reality Spine System is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a bony anatomical structure, such as the spine or pelvis, can be identified relative to CT images of the anatomy. This can include spinal implant procedures, such as pedicle screw placement, where the surgeon wants to see a tracked instrument location in relationship to the stereotaxic display of the CT images of the anatomy.

The optical head mounted display of the OnPoint Augmented Reality Spine System displays 2D stereotaxic screens and an optional

virtual anatomy screen, paired with optional graphical targeting tools and alphanumeric displays. The stereotaxic screen is indicated for correlating the tracked instrument location to the registered patient images. The virtual screen is indicated for displaying the virtual instrument location in relation to the virtual anatomy to assist in percutaneous visualization and trajectory planning. The graphical targeting tools and alphanumeric display are indicated for providing visual and quantitative tracking information of the tracked instrument location including deviation from plan.

The virtual display should not be relied upon solely for absolute positional information and should always be used in conjunction with the displayed stereotaxic information.

## Indications for Use Comparison 21 CFR 807.92(a)(5)

The indications for use for the OnPoint Augmented Reality Spine System are the same as the predicate device.

## Technological Comparison 21 CFR 807.92(a)(6)

The OnPoint Augmented Reality Spine System is the same in its technological features to the predicate device. Both systems include the same hardware and software components, with the following basic components: software, optical head mounted display, tracking camera, rigid spinal or pelvic reference point, and reusable instrument adapters.

## Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Registration testing was successfully completed using an additional 3D scanner with the OnPoint Augmented Reality Spine System; Testing demonstrated that the device is safe for its intended use and is substantially equivalent to the predicate device.

The modified OnPoint Augmented Reality Spine System is substantially equivalent to its predicate, the cleared OnPoint Augmented Reality Spine System. The modified OnPoint Augmented Reality Spine System has the same intended use, technological characteristics, and principles of operation as the predicate. None of the minor differences in compatibility raise new types of safety or effectiveness questions. Performance data demonstrated that the modified OnPoint Augmented Reality Spine System functions as intended.