January 19, 2024

Jessica Traver
Co-Founder & CEO
1940 Fountain View Drive
Houston, TX 77057

Re: DEN220009
Trade/Device Name: VerTouch Spinal Imaging Device
Regulation Number: 21 CFR 886.1985
Regulation Name: Spinal imaging system for neuraxial procedures
Regulatory Class: Class II
Product Code: QXD
Dated: January 31, 2022
Received: February 1, 2022

Dear Jessica Traver:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the VerTouch Spinal Imaging Device, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> VerTouch is indicated to aid in the localization of a lumbar interspinous space, and the marking of an identified insertion site, for diagnostic and therapeutic neuraxial procedures.
>
> VerTouch is indicated for use in hospital facilities and clinics by right- and left-handed emergency medicine, neurology, anesthesiology, and pain medicine professionals for assistance with spinal punctures.
>
> The VerTouch handle is intended to be held with the left hand. Imaging and marking are intended to be performed with the right hand.
>
> VerTouch is indicated for use on patients at least 18 years of age with BMI ≤42 kg/m2 undergoing the following procedures in the seated or lateral positions:
> - Lumbar punctures
> - Neuraxial anesthesia (spinals, epidurals, and combined spinal-epidurals)
> - Epidural steroid injections
> - Epidural blood patches
>
> VerTouch can only be used with the marker included in the VerTouch Kit.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the VerTouch Spinal Imaging Device, and substantially equivalent devices of this generic type, into Class II under the generic name spinal imaging system for neuraxial procedures.

FDA identifies this generic type of device as:

> **Spinal imaging system for neuraxial procedures.** A spinal imaging system for neuraxial procedures is a sensor and software system that is used to assist in identification of the interspinous space for neuraxial procedures.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On February 1, 2022, FDA received your De Novo requesting classification of the VerTouch Spinal Imaging Device. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the VerTouch Spinal Imaging Device into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request and your appeal response, FDA has determined that, for the previously stated indications for use, the VerTouch Spinal Imaging Device can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Risks to Health	**Mitigation Measures**
Inaccurate interspinous space identification leading to: • Increased pain • Bleeding • Unintended dural puncture • Injury to other deeper structures	Clinical performance testing Non-clinical performance testing Human factors testing Software verification, validation, and hazard analysis Labeling
Increased procedure time due to improper device use	Clinical performance testing Human factors testing Software verification, validation, and hazard analysis Labeling

Electrical shock or interference with other devices	Electrical safety testing Electromagnetic compatibility testing
Adverse tissue reaction	Biocompatibility evaluation
Infection	Sterilization validation

In combination with the general controls of the FD&C Act, the spinal imaging system for neuraxial procedures is subject to the following special controls:

(1) Clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use and must evaluate:
  (i) Rate of neuraxial procedure success across the intended use population;
  (ii) Procedure time;
  (iii) Adverse events, including pain, bleeding, unintended dural puncture, and injury to other spinal structures; and
  (iv) Comparison of performance to manual palpation or alternative method of determination of the target insertion site.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use and must evaluate the accuracy, repeatability, and resolution of imaging of the underlying anatomy representative of intended use populations.

(3) Human factors testing must demonstrate that the user can correctly use the device based solely on the directions for use.

(4) Software verification, validation, and hazard analysis must be performed. Validation testing must verify and validate proper image construction.

(5) Electromagnetic compatibility and electrical, mechanical, and thermal safety testing must be performed.

(6) The patient-contacting components of the device must be demonstrated to be biocompatible.

(7) Performance testing must demonstrate the sterility of any device components intended to be labeled sterile.

(8) Labeling must include a warning that risks inherent to neuraxial procedures under standard of care conditions are still present with use of the device.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the spinal imaging system for neuraxial procedures they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD&C Act; 21 CFR 1000-1050).

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact Sarah Philpott at (301) 796-6860.

Sincerely,

Denise L. Hampton -S

for Malvina B. Eydelman, M.D.
Director
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health