

**DE NOVO CLASSIFICATION REQUEST FOR
VERTOUCH SPINAL IMAGING DEVICE**

REGULATORY INFORMATION

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.

NEW REGULATION NUMBER: 21 CFR 868.1985

CLASSIFICATION: Class II

PRODUCT CODE: QXD

BACKGROUND

DEVICE NAME: VerTouch Spinal Imaging Device

SUBMISSION NUMBER: DEN220009

DATE DE NOVO RECEIVED: February 1, 2022

SPONSOR INFORMATION:

IntuiTap Medical
1623 W Fulton St.
Chicago, IL, 60612 USA

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.

LIMITATIONS

In patients with the following diagnosed conditions, VerTouch™ cannot reliably be used for needle placement:

- Scoliosis (abnormal lateral curvature of the spine)
- Thoracic kyphosis (abnormal sagittal (outward) curvature of the spine)
- Lumbar lordosis (abnormal sagittal (inward) curvature of the spine)
- Scleroderma (hardening of the skin and connective tissue)
- Ankylosing spondylitis (inflammation and possible fusion of the vertebrae)
- Spinal stenosis (narrowing of the spinal canal, which may be caused by ligament calcification)

VerTouch™ should also not be used in any scenario in which a spinal puncture is not appropriate, including:

- Skin or soft tissue infection near the puncture site
- Uncorrected coagulopathy
- Increased intracranial pressure secondary to cerebral or spinal lesion
- Acute spinal cord trauma
- Allergy to local anesthetic

PLEASE REFER TO THE LABELING FOR A COMPLETE LIST OF WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS.

DEVICE DESCRIPTION

IntuiTap's VerTouch™ Spinal Imaging Device ("VerTouch" or "Device") is intended to provide a two-dimensional (2D) pressure map of posterior spinal anatomy to help the physician plan and approach his/her needle placement during neuraxial procedures. The Device is intended to aid in the localization of an interspinous space, for diagnostic and therapeutic neuraxial procedures, including lumbar punctures, neuraxial anesthesia (spinals, epidurals, and combined spinal-epidurals), epidural steroid injections, and epidural blood patches. The Device includes functionality to guide a marking tool.

Common Use Scenarios

The Device will primarily be used by 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 for placement and stabilization. Scanning and marking are intended to be performed with the right hand. VerTouch is intended to be used by users with any handedness. The process for creating the 2D pressure map to assist in identification of an insertion site will be the same for all users and procedures. Additionally, there may be some variation in workflow depending on preference. VerTouch can only be used with the following:

- Marker included in the VerTouch kit.

Intended Part of the Body Interacted With

The Device is intended to be applied to a patient's lumbar region for a duration similar to that of a standard spinal puncture procedure.

Intended User Profiles

Primary users may include physicians trained in emergency medicine, neurology, anesthesiology, and pain medicine; as well as physician assistants, certified registered nurse anesthetists, and nurse practitioners that are credentialed to perform spinal punctures. Users may have any handedness but are intended to place the Device with their left hand; and to perform scanning and marking with their right hand. In some facilities, secondary users may complete tasks such as, but not limited to, retrieval, assembly, storage, maintenance, and recharging.

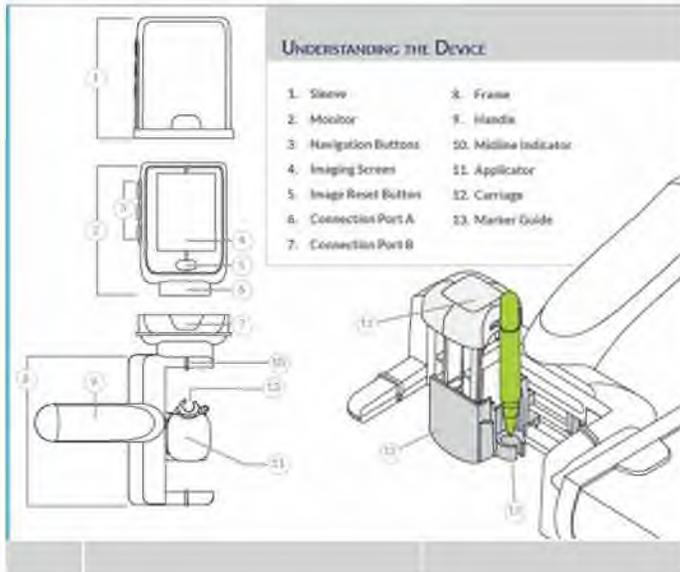
Intended Conditions of Use

The Device is intended for use in a sterile field within hospitals and clinics, with an ambient temperature of 68- 80° Fahrenheit, and relative humidity of 30-65%. In some intended locations of use, such as an operating room or neurology suite, it is likely that the Device would be used under standard conditions (beeping from machines, fluorescent lighting, ambient noise, and conversation, etc.) with a lower likelihood of interruption. In other locations, such as the emergency department, lighting and ambient noise are likely to be typical of a hospital environment with a higher potential for unexpected distractions, louder noises, stressors, and time-constrained interactions.

Summary of Components

Clinical Assembly

VerTouch is a handheld device, capable of assembly and use by a single operator, and requires no connection with peripheral systems or software during clinical use.



The reusable Monitor is powered by a rechargeable Battery, and is the subsystem that performs image acquisition, processing, and display of the TactoMap. The disposables include a Base and a Sleeve, both of which are single use. The Base allows for placement of the Device against the back and includes the interactive components for scanning-based imaging and marker guidance, while the Sleeve prevents contamination from the reusable Monitor during use.

Functional Description

The following sections describe the components as relevant to the broad steps of VerTouch use:

Assembly

Before becoming sterile, the operator retrieves the Monitor from its storage location and places it upside down into the Dock. The operator then opens the pouch and establishes the sterile field by opening the Drape on a table. After becoming sterile, the operator opens the Tray, removes the Base, and connects the base to the Monitor, at which point the Device automatically powers on. The operator then lifts the assembled unit out of the and slides the Sleeve over the Monitor, forming a protective barrier.

Workflow Selection

VerTouch can be used to support needle insertion via marking. With the marking workflow, the device is used to mark an identified insertion site, but local anesthetic (LA) injection and needle insertion occur after device removal. Insertion is then completed after Device removal.

Device Placement

With VerTouch, users continue to use standard landmarking techniques to identify a safe level for the procedure area. This is typically done by palpating for the tips of the iliac crest, which approximately align with the *L4-5 interspinous* space. This is performed prior to draping the

patient, such that the procedure area is exposed and used to guide VerTouch placement. After Device assembly, the user then grips the Handle on the disposable Base with his/her left hand and places the assembled Device against the patient's back. Midline indicators on the device can be used to support alignment with the midline of the spine. A rubber Bottom Pad on the Base prevents slippage of the Device along the back during use.

Imaging

The Applicator is the primary component that facilitates scanning-based tactile imaging. A calibrated, piezoresistive sensor array ("Sensor") is mounted to the patient-contacting surface of the Applicator, which is designed to optimize feature resolution with minimal application of force. The Applicator is assembled with a Carriage mechanism that is mounted to a fixed Track. Via an Applicator Button accessible by the user's right hand, the Applicator can be slid along the craniocaudal (y) axis via the Track; and can be pressed along the anteroposterior axis (z), via a spring mechanism that facilitates 2 cm of tissue penetration. A flexible printed circuit board assembly (PCBA) connects the sensor to downstream electronics and allows for free y- and z-axis movement; an elastomeric (ylock) strip ensures that the Applicator cannot slide while being pressed. When the user presses the Applicator at a first location, a linear positioning system is used to display the corresponding 2D pressure data at that location within the imaging range on the screen. The user then slides the Applicator to a new location and repeats the process until the imaging range is complete. The pressure map element is referred to as the TactoMap. Other GUI elements include a yellow rectangle that corresponds to the current Applicator location, the Crosshair that corresponds to the current Needle Guide location, and a static white Midline Indicator. On the left of the screen is a Force Gauge, which indicates the approximate force of each press to help the user apply the same force across presses. This is calculated based on Sensor output and known active area. Throughout the imaging process, the user observes the outputted pressure data with the goal of identifying a blue region along the midline corresponding to an interspinous space. Navigation Buttons on the left side of the Monitor can be used to adjust screen brightness and/or scanning sensitivity during imaging (on a scale of 0-100, which represents a percentage of the sensor's maximum application pressure). The set sensitivity can be seen in the bar graph on the bottom right of the screen. In the event of any misalignment or no interspinous space, the image can be reset via an operator-facing Reset Button on the Monitor, and scanning can be performed at a new location.

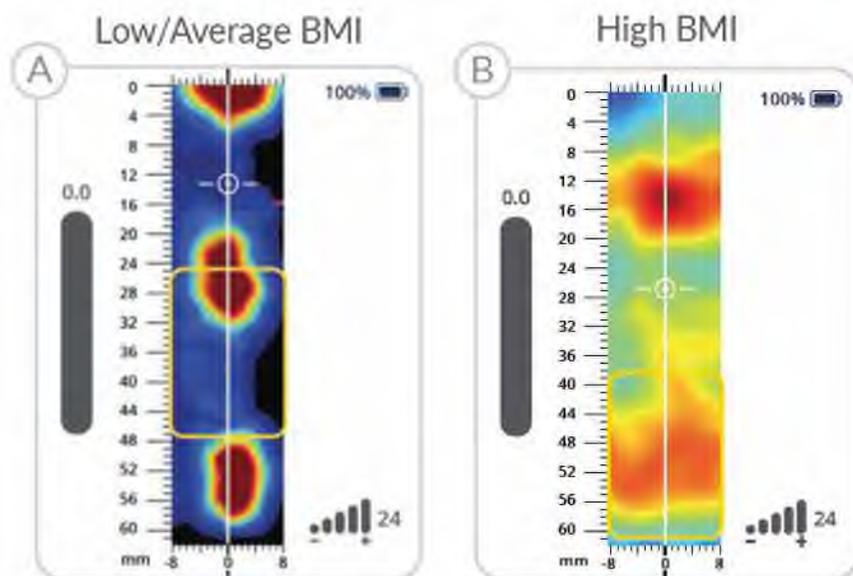


Figure 6. Example of TactoMap

Marking

If marking workflow has been selected, the user places the marker directly through the exposed Marker Guide and marks the insertion site. He/she then removes the Device and injects local anesthetic (LA) and inserts his/her preferred needle on the mark. All Marker Guide interactions are performed with the right hand, per standard needle insertion training, regardless of handedness.

Disassembly

Upon identification of the insertion site, the user completes his/her procedure per standard protocol. Following the procedure, the Sleeve and Monitor are disconnected from the Base. The Monitor is dropped into the Dock, while the remaining components are disposed of with other disposable procedure components.



Figure 8. Rendering of operator dropping the non-sterile Monitor into the Dock, while holding onto the Sleeve.

Monitor Maintenance

After each use, the Monitor is cleaned for visible contaminants. It is then brought to a storage location and placed on the Charging Station. The Power Adapter is used to connect the Charging Station to an outlet to recharge the Monitor. Note that the device cannot be used while charging, as the same connection port on the Monitor allows for connection with the disposable Base and Charging Station.

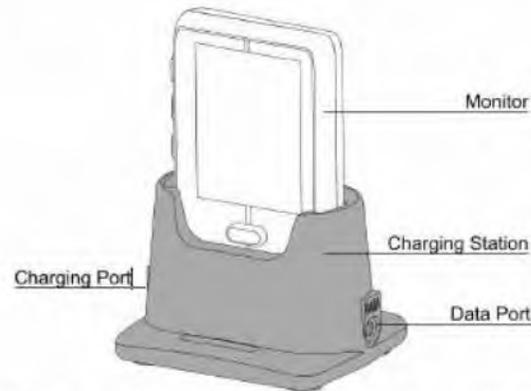


Figure 9. Rendering of the Monitor in the Charging Station, which contains a charging port that the Power Adapter connects to, and a Data Port that the PC Connector connects to. Ports are clearly labeled.

Note that the VerTouch Monitor also has a touchscreen-enabled maintenance mode, which can be operated to adjust time and date settings, to perform firmware updates, and/or to switch the data management functionality between Study and Field Modes (the latter two actions are password-protected).

SUMMARY OF NONCLINICAL/BENCH STUDIES

ELECTROMAGNETIC CAPABILITY & ELECTRICAL SAFETY

Electrical safety and electromagnetic compatibility testing has been performed per IEC 60601-1-12 Edition 1.1 2020-07 CONSOLIDATED VERSION Medical electrical equipment - Part 1-12: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment, and IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.

The test results support electrical safety and electromagnetic compatibility.

MAGNETIC RESONANCE (MR) COMPATIBILITY

The subject device is considered MR Unsafe. Appropriate MR safety symbol is included in the labeling.

SOFTWARE

The VerTouch software documentation was reviewed according to the FDA Guidance document, *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*, issued May 11, 2005. The software was found to have a Moderate Level of Concern. The software documentation included management of cybersecurity and:

1. Software Description
2. Device Hazard Analysis
3. Software Requirements Specification
4. Architecture Design Chart
5. Software Design Specification
6. Traceability Analysis
7. Software Development Environment Description
8. Verification and Validation Documentation
9. Revision Level History
10. Unresolved Anomalies

The software documentation provided in support of the VerTouch was found to be acceptable.

BENCHTOP PHANTOM TESTING

The sponsor provided benchtop performance testing on custom-built lumbar phantoms (both average and high-BMI test fixtures) to validate the accuracy and repeatability of the

imaging technology (performance of the piezoelectric sensor array, software, image resolution, etcetera).

The sponsor provided testing device imaging performance under variable realistic variations in tissue geometries and imaging conditions, including variations in applied force, spinous process size, and spinous process depth (which increases with patient BMI). The provided testing addresses resolution characterization, contrast sensitivity and target detectability in challenging high-BMI scenarios

The testing documentation was found to be acceptable to satisfy nonclinical performance requirements.

HUMAN FACTORS TESTING

The VerTouch™ Summative Usability Validation 2 study was conducted in simulated hospital rooms at an R&D facility called mHUB in Chicago, IL on December 12 – 16, 2022, and at a market research facility in Boston, MA on January 3 – 10, 2023. All participants received training representative of that expected to be provided in clinical practice. After a one-hour training decay, participants performed simulated use tasks with VerTouch™ on custom phantom models designed to adequately simulate realistic human tissues, muscles, and bone. This new usability validation consisted of a 68-person simulated use study with at least 15 participants from each of the following user groups:

Primary Users:

Anesthesia physicians

- Trained to administer neuraxial anesthesia and/or epidural steroid injections (ESIs)
- Practice in Anesthesiology and/or Pain Management (PM) settings; please note that all PM physicians have an anesthesiology background.

Non-anesthesia physicians

- Trained to perform diagnostic and/or therapeutic lumbar punctures (LPs)
- Practice in Neurology or Emergency Medicine (EM) settings

Anesthesia and Non-anesthesia non-physician providers (NPPs)

- CRNAs, nurse practitioners, and physician's assistants
- Trained to perform the same procedures in the same settings (anesthesia, neurology, and emergency medicine)

Secondary Users:

Anesthesia and Non-anesthesia secondary users (RNs, technicians, and medical assistants)

Table 1: User group details

Primary User Groups	User Group Sub-Specialties	Totals
Anesthesia Clinicians	Anesthesiology MD – Attending, Resident, Fellow	13
	Anesthesiology Assist.	1
	Anesthesiology CRNA	7
	Pain Medicine MD	2
Non-Anesthesia Clinicians	EM MD – Attending, Resident, Fellow	9
	EM PA	5
	EM NP	1
	Neurology MD – Attending, Resident, Fellow	6
	Neurology PA	2
	Neurology NP	2
	Neurosurgeon MD	3
	TOTAL	51
Secondary User Groups	User Group Sub-Specialties	Totals
Anesthesia	RN	3
	AN Tech	2
	PM Tech	1
	OR Tech for Anesthesiology	1
Non-Anesthesia	RN	2
	ER Tech	1
	Medical Assistant	1
	RN	3
	NE Tech	1
	OR Tech for NS	2
	TOTAL	17

Residual-Risk Analysis

The root causes were further categorized to identify if and how the usability issues would be addressed. In nearly all cases, the issues did not require a corrective action as they could not result in harm and/or they were already being addressed by an existing element of the device user interface. In two cases, errors were determined to possibly lead to harm and the root cause analysis pointed to the design of the device user interface (UI). These two issues were determined to require mitigation:

- In one instance, the Sterile Sleeve caught while being placed over the Monitor and the procedure was completed with the Reset Button partially exposed, which has the potential to result in a serious harm of contamination.
- In two instances, the user went around the Marker Guide to place a mark as the Marker did not reach the model’s skin, which could have resulted in procedure delay (negligible, considering the delay having been <30 seconds in these cases).

The following corrective actions were taken to address these issues:

- To address the first issue, the instructions for use was updated to include additional notes, and a figure supporting the existing instructions for Sleeve placement, to ensure users adjust the Sleeve such that it fully covers the Monitor, especially the Reset Button.
- The marking issue was rectified by a minor change to the device form factor. The original design of the marker guide had a (b)(4) (b)(4) without impacting the system and its interfacing components in any way, allowing the marker to go further and reach patient skin in the anatomies that challenged the existing design. The change was verified through bench testing. Given that the change has no impact on any other features of the device that users interact with and does not introduce any new usability risks, additional usability validation was not required.

The above two changes to the device user interface addressed the remaining risks identified in this summative study. Following these changes, all risks associated with use of VerTouch™ were addressed to the extent possible.

SUMMARY OF CLINICAL INFORMATION

Two clinical studies were conducted to evaluate the benefits and risks of use of the device. The first pivotal study (referred to as STU-001) was a multicenter, superiority randomized controlled trial (RCT) (n = 90) powered to evaluate needle insertion attempts as compared to manual palpation (including both marking and needle workflows— (note, needle workflows are no longer present in the device)). A second single-center, superiority trial (n = 81) (referred to as STU-002) was designed to evaluate the success of identifying a target insertion site (TIS) with the marking workflow compared to prospective controls of manual palpation and ultrasound.

STU-001

An Open-Label, Parallel, Randomized Study to Evaluate the Performance of Needle Placements for Diagnostic and Therapeutic Neuraxial Procedures, Using a Handheld Tactile Imaging-based Method Versus Palpation

Study Objective

The primary objective was to establish the superiority of VerTouch versus the conventional palpation technique for the number of needle insertion attempts to successfully access the spinal canal in neuraxial procedures (lumbar puncture, epidural anesthesia, spinal anesthesia, combined spinal-epidural anesthesia and epidural blood patch).

Study Population and Locations

Subjects admitted to emergency medicine, neurology, or anesthesiology settings that require a neuraxial procedure as part of their management or work up, and that meet inclusion and

exclusion criteria. 3 study sites included Rhode Island Hospital (orthopedic anesthesia and emergency medicine settings), University of Texas at Houston (obstetric anesthesia and neurology settings), and Medical University of South Carolina (all settings).

Number of Subjects

It was expected that approximately 120 subjects would be screened to meet a target enrollment goal of 96 subjects. Due to COVID concerns, enrollment was closed after a total of 95 subjects were enrolled between April and November 2021. The 27 providers that performed study procedures formed a representative group in terms of their clinical training and procedure experience (9 users were resident physicians). Subjects also formed a representative group in terms of factors that are thought to impact these procedures, such as age, gender, BMI, and procedural positioning (seated vs. lateral).

Recruitment Criteria:

Inclusion Criteria:

Males and females aged 18 years and above, with a body mass index (BMI) $\leq 42\text{kg/m}^2$.

Subjects scheduled for: Diagnostic lumbar puncture (LP), Therapeutic LP, Spinal/epidural/combined spinal-epidural (CSE) anesthesia for planned orthopedic or obstetric procedure, hysterectomy, or total hip/knee replacement, and Epidural blood patch (use of autologous blood to close holes in the dura mater and relieve Post Dural Puncture Headache).

Exclusion Criteria:

Skin or soft tissue infection near the puncture site, Allergy to local anesthetic, Uncorrected coagulopathy Acute spinal cord trauma, History of lumbar spinal surgery, Prior known failed neuraxial anesthesia, Diagnosed scoliosis, thoracic kyphosis, lumbar lordosis, scleroderma, or ankylosing spondylitis, or lumbar spinal stenosis, Incarcerated subjects.

Table 7. Subject Demographics – Intent-To-Treat Population

Summary		VerTouch	Palpation	All Subjects	P-value ¹	
Age (years)	N	42	48	90	0.391	
	Mean	43.8	40.5	42.0		
	SD	17.67	18.47	18.07		
	Median	40.5	33.5	36.0		
	Range	18.0 – 86.0	18.0 – 81.0	18.0 – 86.0		
	Adolescents (< 22) n [%]	2 [4.8%]	3 [6.3%]	5 [5.6%]		0.454
	Young Adults (22-40) n [%]	19 [45.2%]	28 [58.3%]	47 [52.2%]		
	Middle-aged Adult (41-65) n [%]	15 [37.5%]	10 [20.8%]	25 [27.8%]		
Other Adult (> 65) n [%]	6 [14.3%]	7 [14.6%]	13 [14.4%]			
Gender n [%]	Males	13 [31.0%]	12 [25.0%]	25 [27.8%]	0.530	
	Females	29 [69.0%]	36 [75.0%]	65 [72.2%]		
	Pregnant	12 [41.4%]	12 [34.3%]	24 [37.5%]		
	Not Pregnant	17 [58.6%]	23 [65.7%]	40 [62.5%]		
Ethnic Group	Hispanic or Latino	9 [21.4%]	14 [29.2%]	23 [25.6%]	0.353	
	Non-Hispanic or Latino	33 [78.6%]	33 [68.8%]	66 [73.3%]		

Summary		VerTouch	Palpation	All Subjects	P-value ¹	
n [%]	Not Reported	0 [0.0%]	1 [2.1%]	1 [1.1%]		
Race n [%]	Asian	2 [4.7%]	1 [2.1%]	3 [3.3%]	0.965	
	Black or African American	8 [18.6%]	10 [20.8%]	18 [20.0%]		
	Native Hawaiian or Pacific Islander	1 [2.3%]	1 [2.1%]	2 [2.2%]		
	White	27 [62.8%]	32 [66.7%]	59 [65.6%]		
	Other	4 [9.3%]	4 [8.3%]	8 [8.9%]		
Height	N	42	47	89	0.834	
	Mean (cm)	165.7	165.3	165.5		
	SD	9.53	10.36	9.93		
	Median	167.6	162.6	165.0		
	Range	149.0 – 185.4	149.8 – 193.0	149.0 – 193.0		
Weight	N	42	48	90	0.796	
	Mean (kg)	81.6	80.6	81.0		
	SD	19.40	17.71	18.42		
	Median	82.4	79.9	80.5		
	Range	50.8 – 135.8	45.5 – 117.0	45.5 – 135.8		
BMI n [%]	N	42	47	89	0.895	
	Mean (kg/m ²)	29.6	29.4	29.5		
	SD	5.94	6.56	6.24		
	Median	29.9	29.1	29.4		
	Range	19.4 – 40.6	18.3 – 42.0	18.3 – 42.0		
	Underweight (<18.5)	0 [0.0%]	1 [2.1%]	1 [1.1%]		0.631
	Normal (18.5 – 24.9)	10 [23.8%]	15 [31.9%]	25 [28.1%]		
	Overweight (25 – 29.9)	11 [26.2%]	9 [19.1%]	20 [22.5%]		
	Class 1 Obesity (30-34.9)	13 [31.0%]	12 [25.5%]	25 [28.1%]		
	Class 2-3 Obesity (≥ 35)	8 [19.0%]	10 [21.3%]	18 [20.2%]		

¹ P-value from Likelihood Ratio Chi-Square Test or Two-sided T-test with Unequal Variance.

Table 8. Subject Demographics - Per Protocol Population

Summary		VerTouch	Palpation	All Subjects	P-value ¹	
Age (years)	N	25	41	66	0.623	
	Mean	41.4	39.3	40.1		
	SD	15.55	17.78	16.88		
	Median	39.0	33.0	35.0		
	Range	18.0 – 74.0	18.0 – 81.0	18.0 – 81.0		
	Adolescents (< 22) n [%]	1 [4.0%]	3 [7.3%]	4 [6.1%]		0.341
	Young Adults (22-40) n [%]	12 [48.0%]	25 [61.0%]	37 [56.1%]		
Middle-aged Adult (41-65) n [%]	10 [40.0%]	8 [19.5%]	18 [27.3%]			
Other Adult (> 65) n [%]	2 [8.0%]	5 [12.2%]	7 [10.6%]			
Gender n [%]	Males	4 [16.0%]	9 [22.0%]	13 [19.7%]	0.551	
	Females	21 [84.0%]	32 [78.0%]	53 [80.3%]		
	Pregnant	9 [42.9%]	12 [38.7%]	21 [40.4%]		
	Not Pregnant	12 [57.1%]	19 [61.3%]	31 [59.6%]		
Ethnic Group n [%]	Hispanic or Latino	6 [24.0%]	12 [29.3%]	18 [27.3%]	0.538	
	Non-Hispanic or Latino	19 [76.0%]	28 [68.3%]	47 [71.2%]		
	Not Reported	0 [0.0%]	1 [2.4%]	1 [1.5%]		
Race n [%]	Asian	1 [4.0%]	1 [2.4%]	2 [3.0%]	0.907	
	Black or African American	6 [24.0%]	7 [17.1%]	13 [19.7%]		
	Native Hawaiian or Pacific Islander	1 [4.0%]	1 [2.4%]	2 [3.0%]		
	White	16 [64.0%]	29 [70.7%]	45 [68.2%]		
	Other	1 [4.0%]	3 [7.3%]	4 [6.1%]		
Height	N	25	41	66	0.577	
	Mean (cm)	163.5	164.8	164.3		

Summary		VerTouch	Palpation	All Subjects	P-value ¹	
	SD	8.74	10.45	9.79		
	Median	167.0	162.6	162.8		
	Range	149.0 – 185.5	149.8 – 193.0	149.0, 193.0		
Weight	N	25	41	66	0.626	
	Mean (kg)	77.6	79.9	79.0		
	SD	18.44	17.86	17.97		
	Median	75.3	79.4	79.2		
	Range	50.8 – 117.8	45.5 – 117.0	45.5 – 117.8		
BMI n [%]	N	25	41	66	0.740	
	Mean (kg/m ²)	29.0	29.5	29.3		
	SD	6.10	6.37	6.37		
	Median	28.4	29.1	28.5		
	Range	19.4 – 40.5	18.3 – 42.0	18.3 – 42.0		
	Underweight (<18.5)	0 [0.0%]	1 [2.4%]	1 [1.5%]		0.669
	Normal (18.5 – 24.9)	6 [24.0%]	12 [29.3%]	18 [27.3%]		
	Overweight (25 – 29.9)	9 [36.0%]	9 [22.0%]	18 [27.3%]		
	Class 1 Obesity (30-34.9)	5 [20.0%]	10 [24.4%]	15 [22.7%]		
	Class 2-3 Obesity (> 35)	5 [20.0%]	9 [22.0%]	14 [21.2%]		

¹ P-value from Likelihood Ratio Chi-Square Test or Two-sided T-test with Unequal Variance.

Study Endpoints:

Primary Endpoints: Number of insertion attempts (any forward movement of the needle following puncture of the skin) Attempts are counted until confirmation of spinal canal access can be assessed.

Secondary Endpoints:

1. Incidence of first-insertion success (a case that does not require any reinsertions, but can include any number of redirections)
2. Number of redirections (any forward movement of the needle in a new direction not preceded by withdrawal from the skin, counted until confirmation of spinal canal access can be assessed)
3. Number of passes (any forward movement of the needle, calculated as the sum of insertions and redirections)
4. Incidence of first-pass success (a case that does not require reinsertions or redirections)
5. Subject discomfort during landmarking on a Numerical Rating Scale
6. Provider confidence with the identified insertion site on a 1-5 Likert scale
7. Procedure success as confirmed by the following procedure-specific methods:
 - Epidural anesthesia: able to achieve a T10 or greater bilateral sensory level change to cold.
 - Spinal anesthesia: able to achieve sensory blockade to surgical stimulus at level desired.
 - LP: return of CSF.
 - Blood patch: able to inject homologous blood into epidural space (entry confirmed by loss-of-resistance).

Tertiary Endpoints:

1. Localization time (time from first touch of draped patient to identification of an insertion site; for VerTouch, this is the time from device placement to movement of the applicator to the identified insertion site)
2. Insertion time (time from retrieval of marker or LA assembly until no further needle advancements are made)
3. Number of bone contacts
4. Incidence of referral to radiology

Safety Endpoints:

1. Incidence of post-dural puncture headache (PDPH)
2. Incidence of unintended dural puncture (specific to epidural anesthesia)
3. Incidence of paresthesia during needle insertion (specific to neuraxial anesthesia)
4. Incidence of traumatic tap (results in visible blood aspiration)

Investigational Plan

After Informed Consent was obtained, subjects were randomized 1:1 into two groups via the block randomization method. Standard landmarking techniques were used in both groups to identify the procedure area. For subjects randomized to the tactile-imaging group, VerTouch was used to identify an interspinous space and to place a marker, introducer, or needle. For subjects randomized to the palpation group, the palpation-landmarking method was used. After marker,

introducer, or needle placement, the procedure was continued in the usual manner for subjects in both groups.

A designated study observer within each setting recorded the time to identify an insertion site; time to place the marker, introducer, or needle; number of insertions, re-directions, and bone contacts (counted until confirmation of spinal canal access can be assessed); incidence of procedure success; subject's level of discomfort during landmarking; and provider's level of confidence with the identified insertion site.

Total procedure time, incidence of traumatic taps, and incidence of referrals to radiology or pain management were recorded in all settings. In anesthesiology, incidences of paresthesia, unintended dural puncture, and conversion from spinal to epidural anesthesia, were collected for exploratory analysis, where applicable. Any usability issues or device malfunctions observed during the clinical study were also documented.

Study Results:

Participant Study Flow:

Two populations were identified for the primary analysis, which included:

- An Intent-to-Treat Population (ITT): This population consists of all randomized subjects according to their randomized group.
- A Per-Protocol Population (PP): This population consists of all subjects who received their randomized treatment, did not have an inclusion or exclusion violation, had a procedural success (defined as the ability to confirm entry of the needle into the spinal canal), and did not have a major protocol deviation.

The primary analysis and study results were analyzed using the ITT population. The primary analysis was repeated with the PP population.

Two additional populations were defined for selected analysis. These included:

- An As-Treated Population (AT): This population reflects subjects who were treated, according to the treatment procedure their insertion was ultimately based on.
- A Randomized Treatment Population (RT): This population consists of subjects who received their randomized method of needle placement.

Due to 5 screen failures, 90 subjects were randomized:

- Intention to Treat (ITT) population: 42 VerTouch subjects and 48 palpation subjects.
- Randomized Treatment (RT) population: 30 VerTouch subjects and 46 palpation subjects. 14 subjects from the ITT population did not receive their randomized treatment:
 - 8 VerTouch ITT subjects crossed over to palpation and received that treatment instead.
 - 4 VerTouch ITT subjects did not start with either treatment.
 - 2 palpation ITT subjects did not start with either treatment.

- Per Protocol (PP) populations: 25 VerTouch subjects and 41 palpation subjects. 10 subjects from the RT population had an unsuccessful procedure with their randomized method of needle placement:
 - Within the RT population, providers could not confirm needle placement in 5 subjects in each group (primarily due to patient conditions). (Failures include referrals to radiology.)
- As-Treated Population (AT) population: 28 VerTouch subjects and 52 palpation subjects.
 - 8 VerTouch ITT subjects crossed over to palpation and received that treatment instead.
 - 10 ITT subjects ended up with neither treatment:
 - 4 VerTouch ITT subjects did not start with either treatment.
 - 2 palpation ITT subjects did not start with either treatment.
 - 2 subjects from each ITT group started with their randomized treatment but were referred to radiology after. That is, these 4 subjects were part of the RT population, but not the AT population.

Results: Primary Outcomes:

The analysis of the primary efficacy endpoint in the study, the number of insertion attempts, defined as any forward movement of the needle following puncture of the skin, was reported as a statistically significant difference between the VerTouch group and control group (manual palpation) for the PP population, but not the recommended ITT population. FDA generally advises using the ITT population as the primary analysis set for superiority studies as the ITT principle requires including all randomized subjects in their randomized group, which helps preserve randomization and prevent biased estimates. When the same analysis was performed on the ITT population, the results did not demonstrate statistical significance. In addition, there were 15 device malfunctions in the ITT population, and 6 of these 15 subjects were crossed over to the manual palpation group and had a successful procedure. None of the device malfunctions were associated with adverse events or safety concerns.

The primary effectiveness analysis was based on a bootstrap comparison of the mean number of attempts to complete the spinal puncture. For the ITT population, the mean number of insertions was 1.8 for VerTouch and 2.2 for manual palpation (95% confidence interval: -1.2, 0.3, $p=0.284$); for the PP group, the mean number of insertions was 1.2 for VerTouch and 2.1 for manual palpation (95% confidence interval: -1.5, -0.1, $p=0.022$) (two-sided T-test for null hypothesis that difference in means is equal to 0 with unequal variances, 95% CI based on T-test with unequal variances).

Table 27. Sensitivity Analyses for Number of Insertions

Population	Summary or Analysis	Means by Method		Difference Estimate	95% CI	P-value
		VerTouch	Palpation			
Intent-to-Treat	Number of Subjects (N)	42	48			
	Number of Observations (n)	36	46			
	Bootstrap	1.8	2.2	-0.4 ¹	-1.2, 0.3 ¹¹	0.284 ¹¹
	T-test	1.8	2.2	-0.4 ¹	-1.2, 0.4 ²	0.274 ³
	Non-Parametric	1 ⁴	1 ⁴	0 ⁵	0, 0 ⁶	0.185 ⁷
	Log Transformed	1.4 ¹³	1.7 ¹³	0.84 ⁸	(0.63, 1.11) ⁹	0.212 ¹⁰
Per-Protocol	Number of Subjects (N)	25	41			
	Number of Observations (n)	25	41			
	T-test	1.2	2.1	-0.8 ¹	-1.5, -0.1 ²	0.022 ³
	Non-Parametric	1 ⁴	1 ⁴	0 ⁵	0, 0 ⁶	0.036 ⁷
	Log Transformed	1.1 ¹³	1.6 ¹³	0.73 ⁸	(0.57, 0.93) ⁹	0.014 ¹⁰
Randomized Treatment	Number of Subjects (N)	30	46			
	Number of Observations (n)	29	46			
	Bootstrap	1.4	2.2	-0.8 ¹	-1.5, -0.2 ¹¹	0.008 ¹¹
	T-test	1.4	2.2	-0.8 ¹	-1.5, -0.2 ²	0.015 ³
	Non-Parametric	1 ⁴	1 ⁴	0 ⁵	-1, 0 ⁶	0.039 ⁷
	Log Transformed	1.2 ¹³	1.7 ¹³	0.73 ⁸	(0.57, 0.94) ⁹	0.016 ¹⁰
As Treated	Number of Subjects (N)	28	52			
	Number of Observations (n)	28	49			
	Bootstrap	1.3	2.2	-0.9 ¹	-1.6, -0.3 ¹¹	0.003 ¹¹
	T-test	1.3	2.2	-0.9 ¹	-1.6, -0.3 ²	0.007 ³
	Non-Parametric	1 ⁴	1 ⁴	0 ⁵	-1, 0 ⁶	0.032 ⁷
	Log Transformed	1.2 ¹³	1.7 ¹³	0.71 ⁸	(0.56, 0.91) ⁹	0.008 ¹⁰

¹ Difference in means.

² 95% CI based on T-test with unequal variances.

³ Two-sided T-test for null hypothesis that difference in means is equal to 0 with unequal variances.

⁴ Median number of insertions.

⁵ Median difference in VerTouch and Palpation number of attempts.

⁶ Hodges-Lehmann 95% CI for median difference.

⁷ Two-sided Wilcoxon Test, null hypothesis is that groups have a similar location.

⁸ Exponential value of mean of log values for VerTouch minus mean of log values for Palpation.

⁹ 95% CI based on exponential of 95% CI from T-test of log-transformed times.

¹⁰ Two-sided T-test for null hypothesis that difference in means of log is equal to 0 with unequal variances.

¹¹ Based on bootstrap with re-sampling.

¹² Two-sided T-test for null hypothesis that difference in the mean number of attempts is equal to 0 with unequal variances.

¹³ Geometric mean.

Additional characteristics of the ITT VerTouch cohort provide support for the device use scenarios and providers. Of the 36 subjects with a procedure attempt, 22 underwent diagnostic or therapeutic lumbar puncture, 4 received a blood patch, and 10 received “other” neuraxial procedure. Of note, while lumbar puncture made up the largest group of performed procedures (i.e., 22), the data were spread across different device uses and provider specialties (i.e., 15 subjects had procedure needle placement, 4 subjects had an introducer placement, and 17 had skin marking using the device; physicians included 15 in anesthesiology, 14 in emergency medicine and 7 in neurology).

Table 28. ANOVA for Number of Insertions – Intent-To-Treat Population

Factor	Levels	VerTouch		Palpation		ANOVA Results	
		n	Mean (SD)	n	Mean (SD)	Model Factor	P-value ¹
Site	Rhode Island	12	1.5 (1.00)	15	3.0 (2.24)	Method	0.299
	UT	12	1.7 (1.07)	17	2.1 (2.45)	Site	0.671
	UMSC	12	2.2 (2.29)	14	1.5 (0.85)	Method x Site Interaction	0.109
Provider Specialty	Anesthesiology	15	1.7 (1.68)	16	2.1 (2.60)	Method	0.452
	Emergency	14	1.7 (1.64)	16	2.6 (2.22)	Provider Specialty	0.844
	Neurology	7	2.1 (1.21)	13	1.8 (0.93)	Method x Provider Specialty Interaction	0.524
Years in Practice	<5 Years	11	1.9 (1.81)	13	1.8 (1.36)	Method	0.148
	5-10 Years	18	1.7 (1.56)	22	1.8 (1.15)	Years in Practice	0.185
	>10 Years	7	1.7 (1.25)	10	3.7 (3.53)	Method x Years in Practice Interaction	0.139
Procedures in Last 12 Months	<5	2	4.0 (4.24)	3	2.3 (1.53)	Method	0.609
	5-25	14	2.0 (1.18)	21	2.3 (1.98)	Procedures in Last 12 Months	0.495
	26-50	4	1.3 (0.50)	5	1.4 (0.55)	Method x Procedures in Last 12 Months Interaction	0.180
	51-100	3	3.0 (3.46)	4	1.3 (0.50)		
	NA	13	1.1 (0.28)	12	2.7 (2.96)		
Neuraxial Procedure	Diagnostic LP	1	1.0 (NA)	2	1.0 (0.00)	Method	0.599
	Therapeutic LP	21	1.9 (1.49)	30	2.3 (1.76)	Procedure	0.325
	Blood Patch	4	2.5 (3.00)	5	3.2 (4.38)	Method x Procedure Interaction	0.994
	Other	10	1.4 (0.97)	9	1.8 (1.39)		
Needle Type	Spinal 20-22G cutting	15	2.0 (1.69)	19	2.5 (2.06)	Method	0.222
	Spinal 20-22G non-cut.	NA	NA	NA	NA	Needle Type	0.590
	Spring >20G	2	1.0 (0.00)	4	3.8 (4.86)	Method x Needle Type Interaction	0.644
	Tuohy	1	1.0 (NA)	1	1.0 (NA)		
	CSE						
VerTouch Workflow	Marking	17	1.5 (1.46)	NA	NA	VerTouch Workflow	0.496
	Introducer Placement	4	1.8 (1.50)				
	Needle Placement	15	2.1 (1.68)				
BMI (kg/m ²)	Underweight (<18.5)	NA	NA	1	1.0 (NA)	Method	0.281
	Normal (18.5-24.9)	8	2.0 (2.14)	14	1.9 (1.21)	BMI Level	0.873
	Overweight (25-29.9)	11	1.5 (0.69)	8	2.5 (3.46)	Method x BMI Level Interaction	0.848
	Class I Obs. (30.0-34.9)	10	1.8 (1.93)	12	2.1 (1.16)		
	Class II Obs. (35.0+)	7	2.0 (1.41)	11	2.6 (2.62)		
Age (years)	Adolescent (<22)	1	1.0 (NA)	3	2.3 (1.15)	Method	0.340
	Young Adult (22-40)	16	1.9 (2.03)	27	2.1 (2.44)	Age Category	0.978
	Middle-Aged (41-65)	14	1.6 (1.01)	10	2.5 (1.65)	Method x Age Category Interaction	0.895
	Older (>65)	5	2.0 (1.41)	6	2.2 (1.33)		
Gender	Female	27	1.9 (1.73)	36	2.2 (2.23)	Method	0.213
	Male	9	1.3 (0.71)	10	2.3 (1.42)	Gender	0.622
					Method x Gender Interaction	0.480	

¹F-Test Type III ANOVA p-value.

Results: Secondary/Exploratory Outcomes

Secondary outcomes were identified and were to be evaluated sequentially if the primary endpoint reached statistical significance with each additional endpoint requiring the preceding analyses to reach statistical significance to be considered. Each hypothesis evaluated the superiority of VerTouch relative to Palpation. Endpoints included: binary success on first attempt success (procedure only required 1 insertion), mean number of re-directions, number of passes (insertions plus re-directions), binary rate of first pass success (one insertion and no re-directions), mean discomfort score, mean provider confidence scores, and binary rate of

procedure success. None of these secondary outcomes reached statistical significance for the device group.

Additionally, the procedure success rate in the ITT population was higher in the manual palpation group (85.4%) versus the device group (71.4%) when analyzed across all device workflows. However, for the 'marking workflow' that is the intended use of the device, the procedure success rate was 87.5% (refer to below post-hoc analysis discussion). Tertiary and exploratory analyses, which were not associated with any pre-planned claims, included total procedural time and contact with bone and were not found to be significantly different between device and palpation methods. Performance of the 'marking workflow' of the device was determined to be satisfactory, especially by supporting the use of VerTouch by non-anesthesiology physicians for the full range of neuraxial procedures (including laterally-positioned patients).

Results: Adverse Events

Three adverse events were recorded in the ITT population. Two of the events occurred in the VerTouch arm of the study, and 1 in the Palpation arm. The event in the Palpation arm consisted of back and shoulder pain, which may have been related to the procedure (determination, possible), and was not related to the device. The two adverse events in the VerTouch arm were an episode of syncope and hemorrhage, occurring in separate subjects. The hemorrhage was determined to be not related to the device and the syncope was determined to be unlikely to be related to the device.

No additional treatment actions were taken for either subject. There was no significant difference between VerTouch and Palpation approaches for additional safety metrics including unintended dural puncture, paresthesia, traumatic taps, referral to radiology or conversion from spinal to epidural.

Post-Hoc Analysis: Clinically Meaningful Results

Further post-hoc analysis of STU-001 results examined the rates of success/failure for cases in which VerTouch was used. For all workflows, VerTouch was used on 35 subjects (42 randomized to the Device arm less the 5 subjects that crossed over with no Device use and the 2 subjects that had no procedure attempted). Of these 35 subjects, 16 recorded the needle/introducer workflow, 17 recorded the marking workflow; and 2 did not record a workflow. Per the protocol, workflow was recorded prior to initiating the procedure, however, 3 cases did not proceed to the stage of marking or placing a needle/introducer through the Device. These 3 cases were excluded in a workflow-specific analysis, resulting in 32 subjects that used the Device and had an insertion. Of the 32 subjects, 16 used needle/introducer and 16 used marking. The rates of success/failure for these two subgroups were: Marking: 87.5% (14/16) success, 12.5% (2/16) failure; and Needle/introducer: 68.8% (11/16) success, 31.3% (5/16) failure. With regard to the marking-workflow cases, the success rate is nearly the same as that of

the overall success rate for palpation (89.1%). Considering all marking cases were performed in a sterile fashion for STU-001, these data support the safety and efficacy of a sterile marking workflow.

Overall, the device appears to be safe and as effective as standard of care for the marking workflow, although it was determined that sufficient benefit for the needle workflow was not demonstrated by the study results in STU-001.

STU-002

Does the VerTouch Device Improve Insertion Site Identification for Lumbar Neuraxial Procedures when Compared to Palpation or Ultrasound Guided Site Selection? A Prospective Randomized Controlled Trial

A feasibility study of the VerTouch™ device was performed in the obstetric anesthesiology department at Prentice Women’s Hospital at Northwestern Memorial Hospital (NMH), demonstrating successful use of the device in identifying a target insertion site (TIS) for neuraxial procedures with minimal device education, as published in 2021 (McCroory, E.H. & Vaidyanathan, M. (2020). Feasibility study of a force-sensing resistor device for landmark detection for neuraxial procedures and anesthesiologists’ impact on device improvement. *Journal of Medical Engineering & Technology*, DOI: 10.1080/03091902.2020.1799094). After further development from a prototype to a manufactured unit, a single-center superiority randomized clinical trial was performed in the same department, with prospective controls of palpation and ultrasound (NCT04630171, manuscript submitted for publication). (NMH study number: STU00213282; IntuiTap study number: STU-002). The study evaluated the number of reinsertions, redirections, procedure time, and other endpoints for each methodology, with a hypothesis that the VerTouch group would demonstrate improvements in insertion performance with no significant impact on time. Obstetric anesthesiology fellows were selected as proceduralists for the study due to their extensive experience with neuraxial procedures. The study population was exclusively expectant mothers who consented to placement of lumbar epidural catheters for labor analgesia. Each target insertion site was identified by the randomized technique (VerTouch ‘marking workflow’, ultrasound, or palpation) and then followed with standard lumbar epidural placement in a sterile fashion.

Study Objective:

To determine if there is an identifiable difference in the number of insertions and redirections of the needle for a lumbar neuraxial procedure when the VerTouch device is used, when compared with palpation (current gold standard) or ultrasound guidance (US), for the identification of the procedural insertion site.

Study Endpoints:

The primary endpoint is the combined total number of insertions or redirection of the epidural needle. Secondary endpoints included procedural timing; reinsertions; “confidence in mark” (1 = “not confident at all”; 5 = “very confident”)

Recruitment Criteria:

Inclusion Criteria:

Any adult patients undergoing a neuraxial procedure, including pregnant women who make up a large portion of neuraxial procedures.

Exclusion Criteria:

Patients who do not speak English, have a plastic allergy, special populations such as pediatrics and prisoners. Notably, exclusion criteria did not limit BMI nor spinal deformity of patient. The highest BMI of enrolled subjects was 50.7 kg/m² and spinal anatomical issues included 7 patients with scoliosis/kyphosis, 2 patients with positioning challenges, 2 patients with history of spinal surgery. No patients were enrolled that endorsed a history of prior difficulty with neuraxial procedures.

Study details:

All proceduralists were trained with a brief tutorial by a clinically trained device expert followed by extensive practice on a lumbar model. The device expert was available the first day of their device use, but only by phone later if any issues arose. All insertion videos were reviewed by three blinded observers who independently counted redirections and reinsertions of each procedure. The VerTouch device was used in a non-sterile fashion to mark TIS with kitted marker prior to establishing sterile field and performing lumbar epidural per standard workflow; all patients were in a seated position.

Results:

The following table summarizes study demographics and results. Redirections had an interclass correlation coefficient (ICC) of 0.87, with ICC > 0.75 indicating good reliability. Reinsertion ICC was 0.97, with ICC > 0.90 indicating excellent reliability.

Variable	Palpation (N = 26)	Ultrasound (N = 26)	VerTouch (N = 29)	P-value
Demographics				
Age (years)	34.77±2.8	34.46±3.2	35.14±3.5	0.740
BMI (kg/m ²)	31.16±4.4	31.72±6.2	28.84±4.6	0.100
Height (cm)	163.7±5.0	164.7±6.0	165.8±6.9	0.451
Weight (kg)	83.31±11.0	85.8±16.3	83.51±30.0	0.897
Primary Outcome				
Redirections	2.35±3.9	2.81±3.7	0.72±0.9	0.041
Secondary Outcomes				
Timing Data				
Total Procedure Time (min)	7.88±3.1	9.81±4.1	8.66±2.6	0.121
Start to Mark	0.73±0.5	1.23±0.9	2.38±2.2	<0.001
Start to Local	4.04±1.2	5.50±2.4	6.03±2.3	0.002

Variable	Palpation (N = 26)	Ultrasound (N = 26)	VerTouch (N = 29)	P-value
Mark to Local	3.31±1.1	4.27±1.7	3.66±1.3	0.049
Local to End	3.85±2.9	4.31±2.4	2.62±1.3	0.023
Procedural Data				
Reinsertion	0.50±1.0	0.96±1.5	0.11±0.3	0.017
Confidence in Mark	4.88±0.3	4.35±0.8	3.72±1.4	<0.001

In analysis of the results, the device group is compared to two different control groups, palpation and ultrasound, across demographic variables and the prespecified primary and secondary outcomes. From a rigorous statistical analysis of the reported significant test results, the conclusion that VerTouch is superior to both prospective controls is unsupported but clinically meaningful differences are still apparent. Based on descriptive summaries, in the STU-002 study, the observed mean number of redirections was 0.72±0.9 for VerTouch vs 2.35±3.9 for Palpation and 2.81±3.7 for Ultrasound, suggesting that VerTouch may reduce needle redirections when used to indicate a target insertion site via the ‘marking workflow.’

“Handedness” of the anesthesiologist did not appear to impact performance of the TIS with VerTouch, and an analysis of left- versus right-handed providers found no statistically significant difference in reinsertions and redirections for the device.

Although procedural time with VerTouch (and ultrasound) appears to be longer from start through local, reduction in time from local to end suggests minimizing the most painful phase of epidural placement. Pain scores or any patient reported feedback was not elicited in this study, so this prior statement is hypothetical. Lower proceduralist confidence in mark with the device is anticipated given the novelty of the technique—it is unclear what relevance ‘confidence in mark’ has for supporting safety and/or efficacy of VerTouch. STU-002 provides relevant data that supports safe use of VerTouch as an adjunct tool in TIS marking when used in a nonsterile fashion in seated midline insertion of lumbar epidural catheters by anesthesiologists (without significantly lengthening procedural performance time).

The totality of data from both STU-001 and STU-002 support that the VerTouch can reduce insertions and demonstrate favorable benefit versus risk for the marking workflow as specified in the device’s indications for use statement.

Pediatric Extrapolation

VerTouch is indicated for patients ages 18 and older. For medical devices, the FD&C Act defines patients before their 22nd birthday as pediatric patients. Data from patients between 18-22 were used to support the use of the device in patients over the age of 18. It was appropriate to indicate the device for individuals 18 and older because of this data and patients aged 18 to 21 do not carry additional differences or risks relative to the patient population studied.

LABELING

VerTouch labeling consists of Instructions for Use. The Instructions for Use includes appropriate warnings and cautions associated with over reliance on device output in clinical setting.

Intended Users:

VerTouch™ is intended to be used in hospital facilities and clinics by emergency medicine, neurology, anesthesiology, and pain medicine professionals for assistance with lumbar spinal punctures.

Training requirements for users:

Users will not be required to complete any formal training on the use of the device. However, for the safe and effective use of the device, users will be provided with the instructions for use and the QuickStart guide.

RISKS TO HEALTH

The table below identifies the risks to health that may be associated with the spinal imaging system for neuraxial procedures.

Risks to Health	Mitigation Measures
Inaccurate interspinous space identification leading to: <ul style="list-style-type: none"> • 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

SPECIAL CONTROLS

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.

BENEFIT-RISK DETERMINATION

The risks of the device are based on data collected from clinical studies and a human factors study described above. When used to identify a target insertion site via a marking workflow, the probable risks with device use are contamination of the sterile field, misidentification of the interspinous space (leading to procedural complications like increased pain, time to perform procedure and/or harm to deeper tissues from inaccurate marking), and over-reliance on the device to perform standard neuraxial procedures.

1. Contamination: There are both disposable and non-disposable parts to this device. Both parts are placed on the sterile field in preparation for the procedure, despite the fact that the non-disposable part is not sterile, albeit covered with a sterile sleeve. The non-disposable screen covered in a sterile sleeve comes into contact with the patient's back. Infections in the neuraxium can be catastrophic and result in permanent disability or even death, but this risk incidence is very low and also present with alternative methods of marking that are currently routinely used, such as ultrasound.

2. Complexity: This device is a novel technology that is different from current standard of care techniques. The user would need to fully review the instructions and labeling prior to use of the device for proper use, even for specialty-trained clinicians. This risk could increase with users that are unfamiliar with the anatomy of the spine and/or not experienced with performing neuraxial procedures. It also could contribute to overreliance on this device for less experienced providers to properly troubleshoot these procedures (i.e., allow procedure to proceed without appreciation of the underlying or three-dimensional nature of spinal anatomy).
3. Failure or misidentification of the interspinous space: VerTouch is to be used in conjunction with standard-of-care palpation of typical anatomical landmarks when performing neuraxial procedures--it is not a standalone device. If the TIS mark is off midline or shifted cranio-caudad, this could lead to increased procedural time, contact with bone, increased pain, increased risk of unintended dural puncture and/or trauma to deeper structures.

The probable benefits of the device are also based on data collected from clinical studies as described above.

The clinical data in both STU-001 and STU-002 support the device's ability to safely and effectively identify and mark an insertion site when used as part of a sterile procedure. The uncertainty of clinical benefit remains: does assistance with identifying a target insertion site (TIS) result in a clinically meaningful outcome and does the clinical trial data support this claim? The sponsor presents data from two prospective, randomized clinical trials that both pursue a primary outcome of either number of needle insertion attempts or needle directions to establish the device as a superior tool when used to assist with therapeutic and diagnostic neuraxial procedures (versus controls of either palpation and/or ultrasound). For the first clinical study (STU-001) that tested multiple different workflows of device use, conclusive clinical benefit was limited by lack of statistical significance in the intention-to-treat (ITT) cohort of the first pivotal study; the "per protocol" group (via post-hoc analysis) reached statistical significance for the primary outcome. While this trial was not designed as a non-inferiority study, additional post-hoc analysis for STU-001 suggests that use of VerTouch to assist with neuraxial procedures was no worse than palpation (standard of care). No subjects experienced serious reported adverse events or complications. Although STU-001 included the 'needle-workflow' of the device and did not meet success criteria by rigorous statistical analysis when evaluating the aggregate data, non-inferior performance of the 'marking workflow' of the device was determined to be satisfactory, especially by supporting the use of VerTouch by non-anesthesiology physicians for the full range of neuraxial procedures (including laterally-positioned patients).

The second pivotal study (STU-002) did achieve the primary outcome of fewer needle redirections in the VerTouch cohort when used as part of the "marker workflow" in a labor epidural population. Total procedural time was no different between the device, ultrasound and palpation groups. There were no complications or adverse events observed and 100% procedural success was reported for all subjects.

These summative results from STU-001 and STU-002 support a clinical benefit for VerTouch, in the context of the proposed IFU. The limited data set (both in subject numbers and use scenarios) from the two trials and questionable statistical significance for STU-001 places the uncertainty for benefit at moderate. Additional usability evidence to support device benefit when used by non-physician providers is also presented in the file.

Patient Perspectives

This submission did not include specific information on patient perspectives for this device.

Benefit/Risk Conclusion

In conclusion, given the available information above, for the following indication statement:

VerTouch is indicated to aid in the localization of a lumbar interspinous space and 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 position:

- 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.

The probable benefits outweigh the probable risks for the VerTouch Spinal Imaging Device. The device provides benefits, and the risks can be mitigated by the use of general controls and the identified special controls.

CONCLUSION

The De Novo request for the VerTouch Spinal Imaging System is granted and the device is classified as follows:

Product Code: QXD
Device Type: Spinal imaging system for neuraxial procedures
Regulation Number: 21 CFR 868.1985
Class: II