

# SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

## I. GENERAL INFORMATION

Device Generic Name:	Artificial Cervical Disc
Device Trade Name:	prodisc® C SK prodisc® C Vivo
Device Product Code:	MJO
Applicant's Name and Address:	Centinel Spine, LLC 900 Airport Road, Suite 3B West Chester, PA 19380 Phone: (484) 887-8810
Date of Panel Recommendation:	None
Premarket Approval Application: (PMA Number)	P070001/S025
Date of FDA Notice of Approval:	October 10, 2025

The original PMA (P070001) was approved on December 17, 2007, for the prodisc® C. A subsequent PMA Supplement (P070001 / S019) was approved on July 7, 2022, for the subject prodisc® C SK and prodisc® C Vivo and is indicated in skeletally mature patients for reconstruction of a single disc from C3-C7 following discectomy for intractable symptomatic cervical disc disease (SCDD). Symptomatic cervical disc disease is defined as neck or arm (radicular) pain and/or a functional/neurological deficit with at least one of the following conditions confirmed by imaging (CT, MRI, or X-rays): herniated nucleus pulposus, spondylosis (defined by the presence of osteophytes), and/or loss of disc height. The prodisc® C Total Disc Replacement is implanted via an open anterior approach. Patients receiving the prodisc® C Total Disc Replacement should have failed at least six weeks of non-operative treatment prior to implantation of the prodisc® C Total Disc Replacement.

The subject PMA supplement was submitted to expand the indication for the prodisc® C SK and prodisc® C Vivo to include use of the devices at two (2) contiguous intervertebral levels in the cervical spine.

## II. INDICATIONS FOR USE

The prodisc® C SK and prodisc® C Vivo are indicated for use in skeletally mature patients for reconstruction of the disc from C3-C7 following discectomy at one level or two contiguous levels for intractable radiculopathy (arm pain and/or a neurological deficit) with or without neck pain, or myelopathy due to abnormality localized to the level of the disc space and at least one of the following conditions confirmed by radiographic imaging (CT, MRI, X-rays): herniated nucleus pulposus, spondylosis (defined by the presence of osteophytes), and/or visible loss of disc height

as compared to adjacent levels. The prodisc® C SK and prodisc® C Vivo are implanted using an anterior approach. Patients should have failed at least 6 weeks of conservative treatment or demonstrated progressive signs or symptoms despite nonoperative treatment prior to implantation of the prodisc® C SK and prodisc® C Vivo.

### **III. CONTRAINDICATIONS**

- Fractures, infections, tumors
- Spinal stenosis by hypertrophic spondylarthrosis
- Cervical instability on resting (neutral) lateral or flexion-extension radiographs; translation greater than or equal to 3.5mm and/or greater than 11° of angular difference from either adjacent level
- Ossification of posterior longitudinal ligament (OPLL)
- Cervical anatomical deformity or malalignment (e.g., ankylosing spondylitis, scoliosis, kyphosis) at the operative or adjacent levels or anatomical compromise of the vertebral bodies or vertebral endplates at the operative levels
- Osteoporosis or osteopenia defined as DEXA bone mineral density T-score less than -1.5
- Facet joint degeneration
- Acute or chronic systemic, spinal, or localized infections
- Allergy or sensitivity to cobalt, chromium, molybdenum, titanium or polyethylene

### **IV. WARNINGS AND PRECAUTIONS**

- The warnings and precautions can be found in the prodisc® C SK and prodisc® C Vivo labeling.

### **V. DEVICE DESCRIPTION**

The prodisc® C SK and prodisc® C Vivo are manufactured with chromium molybdenum alloy (Co-28Cr-6Mo (CoCrMo)) endplates (with a commercially pure titanium plasma spray coating) and an ultra-high molecular weight polyethylene (UHMWPE) inlay. The prodisc® C SK device features a midline keel oriented anterior-posterior, while the prodisc® C Vivo features six pegs oriented anterior-posterior on the lateral edges that anchor the devices to the vertebral bodies.



**Figure 1: prodisc® C SK (Left), and prodisc® C Vivo (Right)**

**Table 1** describes the available sizes and configurations of the prodisc® C SK and prodisc® C Vivo components.

**Table 1: prodisc® C SK and prodisc® C Vivo Part Listing and Size Overview**

Implant Type	Catalog Number	Width (mm)	Depth (mm)	Height (mm)
<b>prodisc® C SK</b>				
prodisc® C SK, Size M	PDCM5	15	12	5
prodisc® C SK, Size M	PDCM6	15	12	6
prodisc® C SK, Size M	PDCM7	15	12	7
prodisc® C SK, Size MD	PDCMD5	15	14	5
prodisc® C SK, Size MD	PDCMD6	15	14	6
prodisc® C SK, Size MD	PDCMD7	15	14	7
prodisc® C SK, Size L	PDCL5	17	14	5
prodisc® C SK, Size L	PDCL6	17	14	6
prodisc® C SK, Size L	PDCL7	17	14	7
prodisc® C SK, Size LD	PDCLD5	17	16	5
prodisc® C SK, Size LD	PDCLD6	17	16	6
prodisc® C SK, Size LD	PDCLD7	17	16	7
prodisc® C SK, Size XL	PDCXL5	19	16	5
prodisc® C SK, Size XL	PDCXL6	19	16	6
prodisc® C SK, Size XL	PDCXL7	19	16	7
prodisc® C SK, Size XLD	PDCXLD5	19	18	5
prodisc® C SK, Size XLD	PDCXLD6	19	18	6
prodisc® C SK, Size XLD	PDCXLD7	19	18	7
<b>prodisc® C Vivo</b>				
prodisc® C Vivo, Size M	PDVM5	15	12	5
prodisc® C Vivo, Size M	PDVM6	15	12	6
prodisc® C Vivo, Size M	PDVM7	15	12	7
prodisc® C Vivo MD	PDVMD5	15	14	5
prodisc® C Vivo MD	PDVMD6	15	14	6
prodisc® C Vivo MD	PDVMD7	15	14	7
prodisc® C Vivo L	PDVL5	17	14	5
prodisc® C Vivo L	PDVL6	17	14	6
prodisc® C Vivo L	PDVL7	17	14	7
prodisc® C Vivo LD	PDVLD5	17	16	5
prodisc® C Vivo LD	PDVLD6	17	16	6
prodisc® C Vivo LD	PDVLD7	17	16	7
prodisc® C Vivo XL	PDVXL5	19	16	5
prodisc® C Vivo XL	PDVXL6	19	16	6
prodisc® C Vivo XL	PDVXL7	19	16	7
prodisc® C Vivo XLD	PDVXLD5	19	18	5
prodisc® C Vivo XLD	PDVXLD6	19	18	6
prodisc® C Vivo XLD	PDVXLD7	19	18	7

## **VI. ALTERNATIVE PRACTICES AND PROCEDURES**

There are several other alternatives for the treatment of intractable radiculopathy due to a single-level or multi-level abnormality localized to the level of the disc space at one or two contiguous levels.

- Nonoperative alternative treatments, which include, but are not limited to, simple neck adjustments, physical therapy, heat, traction, braces, bed rest, medications, spinal injections, or exercise programs.
- Surgical alternatives, which include, but are not limited to:
  - Surgical decompression alone
  - Surgical decompression via an anterior approach with fusion using various bone grafting and anterior plating techniques
  - Surgical decompression with fusion using intervertebral cages, with various bone grafting techniques, with or without supplemental anterior plating
  - Decompression with posterior spinal systems (e.g., rods, screws, hooks, wires)
  - Another FDA-approved artificial cervical disc

Each option has advantages and disadvantages. Patients should fully discuss the available alternatives with his or her physician to select the option that best meets their clinical condition, lifestyle, and expectations.

## **VII. MARKETING HISTORY**

The original PMA (P070001) was approved on December 17, 2007, for the prodisc® C. The subject prodisc® C SK and prodisc® C Vivo devices were approved by FDA for one-level indications on July 7, 2022, under P070001/S019. Additionally, the prodisc® C Vivo has been marketed outside of the United States since 2011. The prodisc® C Vivo is currently distributed in: Argentina; Australia; Brazil; Canada; Columbia; Dubai; European Union; Hong Kong; Indonesia; Malaysia; Mexico; Qatar; Saudia Arabia; Singapore; South Africa; South Korea; Switzerland; Taiwan; Thailand; Turkey; United Kingdom; and Vietnam. The prodisc® C SK and prodisc® C Vivo have not been withdrawn from any distribution/marketing in any country for safety or effectiveness reasons.

## **VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH**

Below is a list of the potential adverse effects (e.g., complications) identified from the prodisc® C SK and prodisc® C Vivo clinical study results, approved device labeling for other cervical total disc replacement devices, and published scientific literature including: (1) those associated with any surgical procedure; (2) those associated with anterior cervical spine surgery; and (3) those associated with a cervical artificial disc device, including the prodisc® C SK and prodisc® C Vivo. In addition to the risks listed below, there is also the risk that surgery may not be effective in relieving symptoms or may cause worsening of symptoms. Additional surgery may be required to correct some of the adverse effects.

### *Risks Associated with Any Surgical Procedure*

General surgical risks include, but are not limited to:

- Infection/abscess/cyst, localized or systemic
- Pain at surgical site

- Blood clots, including pulmonary emboli
- Medication and anesthesia reactions
- Phlebitis
- Pneumonia
- Atelectasis
- Soft tissue damage
- Septicemia
- Hemorrhage possibly requiring a blood transfusion, with possible transfusion reaction
- Myocardial infarction
- Paralysis
- Poor tissue healing
- Cerebrovascular accident (CVA)
- Death

### Anterior Cervical Surgery Risks

Anterior cervical surgical risks include, but are not be limited to:

- Infection/abscess/cyst, localized or systemic
- Injury or damage to the trachea, esophagus, nerves or blood vessels
- Dysphagia
- Hoarseness
- Vocal cord paralysis
- Paresis
- Recurrent laryngeal nerve palsy
- Soft tissue damage
- Spinal cord damage
- Dural tear with cerebrospinal fluid leakage
- Arm weakness or numbness
- Bowel, bladder or sexual dysfunction
- Nerve root injury
- Airway obstruction
- Epidural hematoma or bleeding
- Epidural fibrosis
- Vertebral body fracture
- Dysesthesia or numbness
- Paresthesia
- Unresolved pain
- Surgical intervention at incorrect level
- Need for supplemental fixation
- Spinal instability
- Death

### Cervical Artificial Disc Risks

Risks specific to cervical artificial discs, including the prodisc® C SK and prodisc® C Vivo, include but are not limited to:

- Infection/abscess/cyst, localized or systemic
- Allergic reaction to the implant materials
- Implant failure
- Device migration
- Device subsidence
- Device fatigue or fracture or breakage
- Device instability
- Separation of device components
- Placement difficulties, device malposition
- Improper device sizing
- Excessive device height loss
- Wear debris
- Disc space collapse

- Material degradation
- Excessive facet loading
- Kyphosis or hyper-extension
- Loss of flexibility
- Asymmetric range of motion (ROM)
- Vertebral body fracture
- Spinal cord damage,
- Dural tear with cerebrospinal fluid leakage
- Soft tissue damage
- Epidural fibrosis
- Nerve injury, paralysis or weakness that is temporary or permanent
- Injury or damage to the trachea, esophagus, or blood vessels
- Epidural hematoma or bleeding
- Dysesthesia or numbness
- Paresthesia
- Failure to relieve symptoms including unresolved pain
- Additional surgery due to loss of fixation, infection or injury
- Spontaneous fusion due to heterotopic ossification (HO), development of bridging bone or osteophytes
- Periarticular calcification and fusion
- Development of spinal conditions, including but not limited to spinal stenosis, spondylolisthesis, or retrolisthesis
- Removal, revision, reoperation or supplemental fixation of the disc
- Osteolysis, bone loss, or bone resorption
- Death

For the specific adverse events that occurred in the prodisc® C SK and prodisc® C Vivo 2-Level clinical study, please see **Section X**.

**IX. SUMMARY OF NON-CLINICAL STUDIES**

A variety of testing was conducted to characterize the performance of the prodisc® C SK and prodisc® C Vivo for one-level use (and is also applicable for two-level use), including:

- Static Axial Compression
- Dynamic Axial Compression
- Static Compression-Shear
- Dynamic Compression-Shear
- Subluxation
- Device Expulsion
- Static Inlay Expulsion
- Subsidence
- Mode I Wear Testing
- Mode III (Third Body) Wear Testing
- Mode IV (Impingement) Wear Testing
- Dynamic Creep Relaxation
- Cadaver Study
- Explant Analyses and Evaluations
- MR Compatibility
- Coating Testing
- Biocompatibility / Toxicity / Neurotoxicity
- Device Sterilization
- Shelf Life and Transit Validation

**Table 2: Non-Clinical Study Summary**

Test Name	Purpose	Test Method*	Acceptance Criteria	Results
<b>Static and Dynamic Strength</b>				
<b>Static and Fatigue under Axial Compression</b>	Verify static and fatigue performance under simulated physiologic conditions are sufficient to withstand in vivo compressive loads	Six (6) prodisc® C specimens were tested under static compression in 37°C deionized water at a rate of 12mm/min until failure or capacity of load cell was reached.	Must withstand the maximum compression force during maximum flexion (1164N)	Average Static compression force of 24,072N
		Six (6) prodisc® C specimens were tested under dynamic compression in 37°C 0.9% saline to 10,000,000 cycles, using a sinusoidal wave form at 5 Hz.  Testing per ASTM F2346	Fatigue load (10 x 10 <sup>6</sup> cycles runout) ≥ 150 N  Average residual height loss after runout ≤1.5mm	Runout ≥ 1500 N  All acceptance criteria were met.

Test Name	Purpose	Test Method*	Acceptance Criteria	Results
<b>Static and Fatigue Shear Strength</b>	Verify that the static and fatigue performance are sufficient to withstand anticipated in vivo shear compressive loads	<p>Six (6) prodisc® C specimens were tested under static compression-shear at a rate of 12mm/min until failure or capacity of load cell was reached.</p> <p>Six (6) prodisc® C specimens were tested under dynamic compression-shear to 10,000,000 cycles using a sinusoidal wave form at 5 Hz.</p>	<p>Must withstand the maximum compression force during maximum flexion (1164N)</p> <p>Must withstand the maximum forces in dynamic loading (150N)</p>	<p>Average static compression shear ultimate force of 12,945.7N</p> <p>Runout at 600N in dynamic compression-shear</p> <p>All acceptance criteria were met.</p>
<b>Subluxation/Expulsion</b>				
<b>Subluxation</b>	Characterize the force needed to result in subluxation of the prodisc® C	Six (6) prodisc® C specimens were placed within the pockets of stainless steel test blocks with a preload of 100N applied along the Z-axis. The testing was performed in displacement control at a rate of 5mm/minute until the superior endplate disassociated from the inlay and complete subluxation occurred.	Subluxation force $\geq 2$ N	<p>Average subluxation force of 120.4N with 0.43mm of displacement</p> <p>Acceptance criteria met</p>
<b>Device Expulsion</b>	Characterize the prodisc® C mechanical properties via static expulsion testing on the complete implant assemblies	<p>Nine (9) prodisc® C specimens were placed between Grade 15 polyurethane foam test blocks with an axial preload of 100N. A 4.7mm flat point load was used to push against the prodisc® C Vivo and prodisc® C SK devices, and a 5.85mm x 2.4mm flat point load was used to push against the prodisc® C Nova (out-of-scope). The static expulsion tests were performed at a rate of 6mm/minute.</p> <p>Additional expulsion testing conducted on 3 prodisc® C Vivo, SK and Nova (out-of-scope) M5 devices and 3 prodisc® C Vivo, SK, Nova (out-of-scope) XLD7 devices was conducted.</p>	Must withstand the largest occurring in-vivo antero-posterior shear load of 135N	<p>Average expulsion forces for prodisc® C Vivo: <math>382.4 \pm 2.7</math>N with <math>0.97 \pm 0.27</math>mm of displacement</p> <p>Average expulsion forces for prodisc® C SK: <math>274.8 \pm 17.9</math>N with <math>1.35 \pm 1.36</math>mm of displacement</p> <p>Additional subsidence testing demonstrated that the endplate geometry does not impact subsidence performance relative to the original prodisc® C implant.</p> <p>All acceptance criteria met</p>

Test Name	Purpose	Test Method*	Acceptance Criteria	Results
<b>Static Inlay Expulsion Test</b>	Characterize the prodisc® C mechanical properties via static expulsion testing on the inlays from the mating inferior endplates	Six (6) prodisc® C specimens were placed within the pockets of the test blocks. A 5.85mm x 2.4mm flat point load was used to push against the prodisc® C Vivo, and a 4.7mm flat point load was applied against the prodisc® C Nova (out-of-scope). The testing was conducted in displacement control at a rate of 6 mm/minute.	Must withstand the largest occurring in-vivo antero-posterior shear load of 135N	Average inlay expulsion force for prodisc® C Vivo: 349.6 ± 8.3N with 1.57 ± 0.28mm of displacement Additional expulsion testing demonstrated that the endplate geometry does not impact expulsion performance relative to the original prodisc® C implant.  All acceptance criteria met
<b>Subsidence</b>	Characterize the prodisc® C mechanical properties per static subsidence testing	Six (6) prodisc® C Vivo and six (6) prodisc® C SK specimens were placed between Grade 15 polyurethane foam blocks for an overall test height of 40mm. The testing was performed in displacement control at a rate of 6 mm/minute.  Additional subsidence testing conducted on 3 prodisc® C Vivo, SK and Nova (out-of-scope) M5 devices and 3 prodisc® C Vivo, SK, Nova (out-of-scope) XLD7 devices was conducted.	Must withstand loads greater than maximum axial load that a cervical intervertebral disc can withstand (75N)	Average subsidence yield force for prodisc® C Vivo: 1081 ± 23N with an average yield displacement of 2.67 ± 0.18mm Average subsidence yield force for prodisc® C SK: 1067 ± 17N with an average yield displacement of 2.59 ± 0.13mm  All acceptance criteria were met.
<b>Wear</b>				
<b>Device Wear, Mode I</b>	Characterize the Mode I wear performance of the device	Mode I wear testing was conducted per ISO 18192-1 and/or ASTM F2423 guidelines. Four (4) prodisc® c Vivo M5 and four prodisc® C Nova XLD7 (out-of-scope) devices provided and remained lubricated at room in Hyclone Wear Test Fluid. Six (6) assemblies were subjected to 10,000,000 wear cycles at 2.0 Hz.  A comparison of explanted devices to Mode I wear testing was conducted.	Wear rates to be less than the wear rate documented for total hip and knee arthroplasty, which are reported as 30 mg/million cycles and 34 mg/million cycles respectively. The wear rate should be equivalent to other cervical devices on the market (such as 1.546 ±	On average the prodisc® C Vivo M5 mass loss was 12.32 ± 2.6 mg.  The average mass wear rate of the core through 10.0 MC was 1.2 ± 0.4 mg/MC for the Vivo. This corresponds to a volumetric wear rate of 1.3 ± 0.4 mm <sup>3</sup> /MC for the Vivo.  MicroCT analysis demonstrates that the maximum bearing surface penetration depth is 0.4 mm.  The surface roughness results confirm

Test Name	Purpose	Test Method*	Acceptance Criteria	Results
			0.075mg/MC for Mobi-C)	<p>microabrasive polishing of the articulating region of the prodisc® C Vivo M5 articulating surfaces. For the prodisc® C Vivo M5 superior endplate, the articulating surfaces increased in average surface roughness over the duration of the tests, which is also consistent with abrasion of the articulating surfaces.</p> <p>The comparative testing demonstrated that the Mode I Wear testing was adequate at predicting Mode I wear behavior.</p> <p>All acceptance criteria were met.</p>
<b>Wear, Mode III (Third Body)</b>	To characterize the Mode III or 3rd Body wear performance of the device	<p>Testing was conducted to ISO 18192-1 and/or ASTM F2423 unless specified otherwise. A 5 million cycle (MC) was completed to assess the wear rate and wear mechanisms of the prodisc® C Vivo and prodisc® C Nova (out-of-scope) and changes in surface roughness to the articulating surfaces of the devices. Four (4) prodisc® C Vivo M5 and four (4) prodisc® C Nova XLD7 (out-of-scope) devices were provided, and three assemblies of each were assigned as wear test samples and one assembly was assigned as load soak control and one UHMWPE Inlay was assigned as a soak control.</p> <p>A comparison of explanted devices to Mode III wear testing was conducted.</p>	The wear rate is to be less than the wear rate documented for total hip and knee arthroplasty, which are reported as 30 mg/million cycles for knee and 34 mg/million cycles for hips. The wear rate should be equivalent or greater than the wear mode I testing of prodisc® C US testing.	<p>On average, the prodisc® C Vivo M5 mass loss was <math>7.5 \pm 1.4</math> mg.</p> <p>The average mass wear rate of the core through 5.0 MC was <math>1.5 \pm 0.3</math> mg/MC.</p> <p>Volumetric wear rate of <math>1.6 \pm 0.3</math> mm<sup>3</sup>/MC.</p> <p>The maximum penetration across all wear stations experienced by the Inlay was less than 0.2mm.</p> <p>The comparison of in vivo retrieved and Wear Mode III (3rd Body) test prodisc® cervical devices suggests the Wear Mode III test is adequate for predicting the wear behavior under abrasive and/or 3rd Body conditions.</p> <p>All acceptance criteria were met.</p>
<b>Wear, Mode IV (Impingement)</b>	Evaluate the Mode IV, or impingement, wear	Test methods met ASTM F3295-18 guidelines unless specified otherwise. There	N/A (for characterization purposes)	After 1 million cycles, no devices demonstrated fracture, delamination, or

Test Name	Purpose	Test Method*	Acceptance Criteria	Results
	performance of the prodisc® C Nova XLD5 (out-of-scope)	<p>were eight (8) prodisc® C Nova XLD5 (out-of-scope) constructs provided to the testing facility. One (1) assembly was assigned as load soak control, six (6) assemblies were assigned as wear test samples, and one (1) UHMWPE Inlay was assigned as a soak control. Testing was performed to 10 MC, stopping every 0.25 MC.</p> <p>A comparison of explanted devices to Mode IV wear testing was conducted.</p>		<p>any signs of functional failure.</p> <p>On average the UHMWPE inlay and superior endplate (total) mass loss was <math>2.3 \pm 0.3</math> mg and <math>0.3 \pm 0.2</math> mg, respectively.</p> <p>The average mass wear rate of the inlay and superior endplate through 1.0 MC was <math>2.4 \pm 0.3</math> mg/MC and <math>0.2 \pm 0.2</math> mg/MC, respectively. This corresponds to a volumetric wear rate of <math>2.7 \pm 0.3</math> mm<sup>3</sup>/MC for the inlay and <math>0.02 \pm 0.02</math> mm<sup>3</sup>/MC for the superior endplate.</p> <p>The comparison of the US prodisc® C and US prodisc® C Vivo retrieved and Mode IV Wear test prodisc® cervical devices suggests the Wear Mode IV test is adequate for predicting the wear behavior under Mode IV, impingement, conditions.</p>
<b>Wear Particle Analysis</b>	Evaluate wear particles per ASTM F1877.	Wear fluid was assessed up to 10.0 MC (1.0, 2.5, and 10.0 MC) to analyze wear debris from the US prodisc® C Vivo and prodisc® C Nova (out-of-scope) UHMWPE inlay per ASTM F1877.	N/A (for characterization purposes)	The results of this analysis supported that the sizes and morphologies of particles found from the in vitro testing of the US prodisc® C product family are consistent with the expectations for UHMWPE on CoCrMo alloy bearing couples.
<b>Dynamic Creep</b>				
<b>Dynamic Creep Relaxation</b>	Determine the creep characteristic of the UHMWPE inlay of the prodisc® C disc replacement	The creep relaxation test was completed by executing the normal wear Mode I testing procedure. Before and after testing, the polyethylene inlay was imaged using a $\mu$ CT 80 (Scanco Medical AG, Switzerland) at a maximum voxel resolution of 18 $\mu$ m	The plastic deformations should be smaller than the diurnal changes of the intervertebral disc (1.5mm).	MicroCT analysis demonstrates that the maximum bearing surface penetration depth is 0.4mm. All acceptance criteria were met.

Test Name	Purpose	Test Method*	Acceptance Criteria	Results
<b>Cadaver Study</b>				
<b>Low Endurance Testing</b>	Perform low endurance cyclic tests on the four prodisc® endplate fixation variants to assess immediate fixation	The coupled eccentric loading (CEL) protocol was used to cyclically move the specimens through a sequence of combined motions of flexion or extension with right and left axial rotation. The end limits of motion were established for load limits of 1.5 Nm in flexion, extension and axial rotation (or a combined moment of 2.1 Nm) along with a compressive load of 50 N applied to the upper mounting pot directly above the midline of the disc implant. Each specimen was cycled 2000 times and measures of implant endplate migration were made after 20 initial cycles and at cycle increments of 250, 500, 1000, 1500, and 2000.	N/A	<p>Two segments exceeded the maximum limit of 15° during flexion but no specimens exceeded the combined sagittal plane rotation of 30°. If the alignment of the implant during the potting procedure was not parallel to the transverse plane, the end ROM could exceed the allotted maximum value of 15°. All of the specimens were under the allowable 10° of axial rotation.</p> <p>All but one of the of the specimen migration values were below threshold acceptance of 0.3 mm. The upper endplate of specimen 7A (original PDC) reached 0.36 mm. Referring back to the maximal failure limit of 3 mm, the mean migration values of the upper component ranged between 0.02 mm and 0.08 mm or 0.7% and 2.7% of the failure limit (3 mm), respectively, and between 0.01 mm and 0.04 mm or 0.3% and 1.3% of the failure limit (3 mm), respectively, for the lower components. Overall, no significant differences occurred between the upper endplates of any of the four implants or between any of the lower endplates of any of the four implants.</p>
<b>Shear Expulsion</b>	Determine the failure load required to initially fail and expulse the upper and lower endplates of	The specimens were disarticulated through the disc space and separated into upper and lower segments. Each top and bottom part of the specimen	N/A	No significant differences occurred between the four implants for any of the expulsion test data sets for Peak Expulsion force,

Test Name	Purpose	Test Method*	Acceptance Criteria	Results
	the four different prodisc® C endplate fixation variants	<p>was individually mounted in a vice located on the base plate of the testing platform and oriented with the outer top surface of the respective implant parallel to a vertical reference plane.</p> <p>The gimbal assembly was programmed to move the shear tool against the implant endplate and apply a 50 N compressive load. The gimbal assembly was then programmed to move downward at a rate of 0.32 mm/s causing the shear tool to expulse the implant endplate along the path of insertion.</p>		Failure Initiation Work, Expulsion Work and Resistive Stiffness. No differences were found in the peak force required to expulse the implant as well as with the overall work required to initiate or completely expulse the implant.
<b>MR Compatibility</b>				
Force Measurement	Assess the force effects on prodisc® C designs in the main static magnetic field of 3.0 Tesla	Testing was conducted per ASTM F2052. The implant was suspended with a thin string at the portal of an MR imaging unit and their deflection from the vertical was determined.	<p>The acceptance criteria based on the MRI scanner are as follows:</p> <p>FDA worst case 3T scanner: 25 mT/cm field gradient, &lt;15.5° acceptable angle</p> <p>Philips 1.5T: 45 mT/cm field gradient, &lt;26.5° acceptable angle</p> <p>Philips 3.0T: 90 mT/cm field gradient, &lt;30.2° acceptable angle</p> <p>Siemens Trio 3T: 90 mT/cm field gradient,</p>	<p>All implants showed low force effects far below the limit of the gravitational force of the part.</p> <p>All acceptance criteria were met.</p>

Test Name	Purpose	Test Method*	Acceptance Criteria	Results
			<45° acceptable angle	
Torque Measurement	Assess the torque effects on prodisc® C designs in the main static magnetic field of 3.0 Tesla	Testing was conducted per ASTM F2213. A qualitative evaluation of the torque effects was performed by manually turning the implants at the isocenter of the 3T magnet. Whenever any static torque effects could be sensed, a quantitative torque measurement was performed.	<p>The acceptance criteria based on the MRI scanner are as follows:</p> <p>FDA worst case 3T scanner: 25 mT/cm field gradient, &lt;15.5° acceptable angle</p> <p>Philips 1.5T: 45 mT/cm field gradient, &lt;26.5° acceptable angle</p> <p>Philips 3.0T: 90 mT/cm field gradient, &lt;30.2° acceptable angle</p> <p>Siemens Trio 3T: 90 mT/cm field gradient, &lt;45° acceptable angle</p>	<p>No torque effects were observed with any of the implants. Therefore, no quantitative measurements according to the ASTM standards were performed.</p> <p>All acceptance criteria were met.</p>
Heating Effects	Assess the heating effects due to the Rf-field during MR-scans	Testing followed the general guidelines established in ASTM F2182. The implants were placed in the body shaped ASTM phantom filled with 30 liters of distilled water, 300g PAA and 39.6g NaCl. The conductivity of the gel was $4.8 \pm 0.1$ mS/cm. The temperature changes were continuously measured by fiberoptic temperature probes during the 15-minute minimum time scan.	The whole-body temperature rise should not be greater than 0.5°C for normal mode and 1.0°C for controlled mode.	<p>The temperature increase near the implant ranged from 1.1°C (1.5T) and 1.9°C (3.0T). The distribution of the increase of temperature throughout the body of the subject would result in an overall temperature increase of less than 1.0°C.</p> <p>All acceptance criteria were met.</p>

Test Name	Purpose	Test Method*	Acceptance Criteria	Results
Artifact Size	Estimate the artifact size around the implant	The implant was placed in a tank filled with 8L of CuSo4 solution. The part was placed on a grid and tested both orthogonally and parallel to the main magnetic field. Gradient and Spin-Echo sequences as described in ASTM 2119 were used.	N/A. The objective was to report the size of the artifact.	The maximal artifacts for the two different sequences are as follows:  Implant Aligned with Magnetic Field: 1.5T Scanner, FFE: 7.0cm 1.5T Scanner, SE: 5.5cm 3.0T Scanner, FFE: 8.5cm 3.0T Scanner, SE: 6.5cm  Implant Orthogonal with Magnetic Field: 1.5T Scanner, FFE: 7.0cm 1.5T Scanner, SE: 5.5cm 3.0T Scanner, FFE: 8.0cm 3.0T Scanner, SE: 6.0cm
<b>Coating Characterization</b>				
CP Ti Plasma Spray Coating for Prodisc® Cervical Discs	Characterize the chemically pure titanium (CP Ti) plasma coating processes of the prodisc® cervical disc replacement implants	Testing was conducted per ASTM F1580, ASTM F1147, ASTM B214, ASTM F1044, ASTM F1978	N/A	No new testing was performed as the CP Ti Coating used in the prodisc® C Vivo and prodisc® C SK are identical to the PMA-approved prodisc® C.
<b>Biocompatibility/ Toxicity / Neurotoxicity</b>				
Implant Biocompatibility	Evaluate the biocompatibility risk of the prodisc® C implants	The biocompatibility risk assessment was conducted per ISO 10993-1, ISO 14971, and FDA General Program Memorandum #G95-1	N/A	The prodisc® C Nova (out-of-scope), prodisc® C SK, and prodisc® C Vivo meet the requirements of ISO 10993-1, ISO 14971, and FDA General Program Memorandum #G95-1
Instrument Biocompatibility	Evaluate the biocompatibility risk of the prodisc® C instrumentation	The biocompatibility risk assessment was conducted per ISO 10993-1, ISO 14971, and FDA General Program Memorandum #G95-1	N/A	The instrumentation used with the subject device were cleared for use under Traditional 510(k), K221848
Neurotoxicity	Assess neurologic biocompatibility of the prodisc® C implants	The wear of the articulating and non-articulating surfaces of the prodisc® C Nova (out-of-scope) were estimated using test methods in accordance with consensus standards (for Mode I Wear ASTM F2423 and ISO 18192-1, for Mode III Wear ISO 18912-1, and Mode IV Wear ASTM F3295). For the purposes of	Must be lower than a non-toxic bolus done in a human, which is described in literature as 70mg	The total estimated in vivo mass loss over 10 MC for Mode I, Mode III, and Mode IV testing were all lower than 70mg.  All acceptance criteria were met.

Test Name	Purpose	Test Method*	Acceptance Criteria	Results
		this document, the testing assessed mass loss.		
<b>Device Sterilization</b>				
Implant Sterilization	Validate the gamma radiation sterilization methods for the expanded family of prodisc® C SK, prodisc® C Vivo, and prodisc® C Nova (out-of-scope)	Validation testing was performed per ISO11137-2 using the VDMax <sup>25</sup> sterilization dose method	Sterilization method must achieve a sterility assurance level (SAL) of 10 <sup>-6</sup> with 25kGy as the minimum sterilization dose	Does establishing experiment determined that 25kGy is the minimum dose required for sterilization of the prodisc® C products to achieve a SAL of 10 <sup>-6</sup> .  All acceptance criteria were met.
Instrument Cleaning and Sterilization	Validate the packaging, cleaning, and sterilization methods for prodisc® C instrumentation	N/A	N/A	The cleaning, sterility, packaging, and shelf-life of the Centinel Disc Instruments have been evaluated in a PMA (P070001, P070001/S019), an IDE (G190041), and most recently cleared within a traditional 510(k) (K221848).
<b>Shelf Life and Transit Validation</b>				
Small Punch Test	Characterize the packaging and shelf-life of the prodisc® C implants	Testing was performed to ASTM F2183-02	Average punch strength shall not decrease >20% from the time zero average	All acceptance criteria were met.
Surface Oxidation Test	Characterize the packaging and shelf-life of the prodisc® C implants	Testing was performed to ASTM F2102-06	No value shall exceed a SOI of 1.0	All acceptance criteria were met.
Residual Oxygen Test	Characterize the packaging and shelf-life of the prodisc® C implants	Testing was performed to the Fruh test method	Oxygen value ≤ 2.0%	All acceptance criteria were met.
Leak Test	Characterize the packaging and shelf-life of the prodisc® C implants	Testing was performed to ASTM D3078	Sterile barrier must remain undamaged	All acceptance criteria were met.
Seal Strength Test	Characterize the packaging and shelf-life of the prodisc® C implants	Testing was performed to ASTM F88-06	Seal strength > 1.50 lbf	All acceptance criteria were met.
*Note, the compendium of bench testing is inclusive of the mechanical testing performed on prodisc® C SK, prodisc® C Vivo, and prodisc® C Nova (out-of-scope) which was reviewed and approved under PMA Supplement P070001/S019. The prodisc® C Nova device, which is considered out-of-scope of the subject submission, was				

Test Name	Purpose	Test Method*	Acceptance Criteria	Results
determined to be the worst-case design variant for several of the mechanical tests, which is why it is referenced in several of the tests summarized in the table above.				

## X. SUMMARY OF PRIMARY CLINICAL STUDY

The applicant conducted a clinical study to establish a reasonable assurance of safety and effectiveness of the Centinel Spine prodisc® C SK and prodisc® C Vivo devices for reconstruction of the disc from C3-C7 following discectomy at two contiguous levels for intractable radiculopathy (arm pain and/or a neurological deficit) with or without neck pain, or myelopathy due to abnormality localized to the level of the disc space and at least one of the following conditions confirmed by radiographic imaging (CT, MRI, X-rays): herniated nucleus pulposus, spondylosis (defined by the presence of osteophytes), and/or visible loss of disc height as compared to adjacent levels. to treat radiculopathy/myelopathy. The study was conducted under Investigational Device Exemption (IDE) G190041 in the US. A summary of the clinical study is presented below.

### A. Study Design

Subjects in the pivotal clinical trial were treated between July 2019 and December 2024. The prospective, multi-center, randomized, controlled clinical study was conducted under IDE G190041 to compare the prodisc® C SK and prodisc® C Vivo investigational devices to the Mobi-C control device, a PMA approved artificial cervical disc. The database for this PMA reflects data collected on a total of 480 subjects that were randomized and enrolled in the study; of the 480 subjects, 47 of these subjects, remained blinded, and ultimately were not treated, 433 of these subjects (N=293 prodisc® C SK and prodisc® C Vivo; and N=140 Mobi-C) had an incision time recorded. Subjects were treated at 31 US sites. Subjects in the investigational device arm could receive: treatment at two-levels with prodisc® C SK; treatment at two-levels with prodisc® C Vivo; or, treatment with a prodisc® C SK at one-level and prodisc® C Vivo at a contiguous level. It was determined that the subject device designs were similar enough to allow for different combinations in the investigational group.

Subjects were randomized in a 2:1 ratio to the two-level prodisc® C SK and/or prodisc® C Vivo device (investigational group) or to the two-level Mobi-C device (control group), respectively. A statistical plan was designed to test for non-inferiority between the two groups.

#### 1. Clinical Inclusion and Exclusion Criteria

To be eligible for the IDE study, subjects had to meet all of the inclusion criteria and none of the exclusion criteria in **Table 3**:

**Table 3: Study Inclusion and Exclusion Criteria**

Study Inclusion Criteria	Study Exclusion Criteria
In order to be eligible to participate in this study, subjects must meet all of the following criteria: <ol style="list-style-type: none"> <li>1. Male or female, age <math>\geq 18</math> and <math>\leq 69</math> years.</li> <li>2. Diagnosis of radiculopathy or myeloradiculopathy of the cervical spine, with pain, paresthesia or paralysis in a specific</li> </ol>	Subjects who meet any of the following criteria will be excluded from participating in this study: <ol style="list-style-type: none"> <li>1. Have an active systemic infection or infection at the operative site.</li> </ol>

Study Inclusion Criteria	Study Exclusion Criteria
<p>nerve root distribution C3 through C7, including at least one of the following:</p> <ol style="list-style-type: none"> <li>a. Neck and/or arm pain (at least 30 mm on the 100 mm visual analogue scale [VAS] scale).</li> <li>b. Decreased muscle strength of at least one level on the clinical evaluation 0 to 5 scale.</li> <li>c. Abnormal sensation including hyperesthesia or hypoesthesia; and/or</li> <li>d. Abnormal reflexes.</li> </ol> <ol style="list-style-type: none"> <li>3. Symptomatic cervical disc disease (SCDD) at two contiguous levels from C3 to C7.</li> <li>4. Radiographically determined pathology at the level to be treated correlating to primary symptoms including at least one of the following: <ol style="list-style-type: none"> <li>a. Decreased disc height on radiography, computed tomography (CT), or magnetic resonance imaging (MRI) in comparison to a normal adjacent disc.</li> <li>b. Degenerative spondylosis on CT or MRI.</li> <li>c. Disc herniation on CT or MRI</li> </ol> </li> <li>5. NDI Score <math>\geq 30\%</math></li> <li>6. Unresponsive to non-operative, conservative treatment (rest, heat, electrotherapy, physical therapy, chiropractic care and/or analgesics) with the following conditions: <ol style="list-style-type: none"> <li>a. Approximately six weeks or more of radicular symptoms; or</li> <li>b. Have the presence of progressive symptoms or signs of nerve root/spinal cord compression despite continued non-operative, conservative treatment; or</li> <li>c. Sooner than 6 weeks for worsening symptoms of neurologic compromise.</li> </ol> </li> <li>7. Appropriate for treatment using an anterior surgical approach.</li> <li>8. Reported to be medically cleared for surgery.</li> <li>9. Physically and mentally able and willing to comply with the Protocol, including the ability to read and complete required forms and willing and able to adhere to the scheduled follow-up visits and requirements of the Protocol.</li> <li>10. Written informed consent provided by subject</li> </ol>	<ol style="list-style-type: none"> <li>2. Have a history of or anticipated treatment for active systemic infection, including HIV or Hepatitis C.</li> <li>3. Have more than one immobile vertebral level between C1 to C7 from any cause including but not limited to congenital abnormalities and osteoarthritic “spontaneous” fusions.</li> <li>4. Have previous trauma to the C3 to C7 levels resulting in significant bony or discoligamentous cervical spine injury.</li> <li>5. Have had any prior cervical spine surgery at the operative level(s), i.e., laminotomy.</li> <li>6. Have had a prior cervical TDR or fusion procedure at any level.</li> <li>7. Have axial neck pain in the absence of other symptoms of radiculopathy or myeloradiculopathy justifying the need for surgical intervention.</li> <li>8. Have disc height less than 3 mm as measured from the center of the disc in a neutral position.</li> <li>9. Have radiographic confirmation of severe cervical facet joint disease or degeneration at any level.</li> <li>10. Have osteoporosis or is at increased risk of osteoporosis, defined as a DEXA bone density measured T-score of <math>\leq -1.5</math> or worse (i.e., -1.6, -1.7, etc.).  Note: A qualifying T-score from either the hip or spine may be used to confirm eligibility. For subjects without a DEXA within 24 months of screening, a score of <math>\geq 6</math> on either the SCORE (females) or MORES (males) requires a DEXA to determine eligibility.</li> <li>11. Have Paget’s disease of bone, osteomalacia or any other metabolic bone disease other than osteoporosis, which is addressed above.</li> <li>12. Have active malignancy that included a history of any invasive malignancy (except non-melanoma skin cancer), unless the subject had been treated with curative intent and there had been no clinical signs or symptoms of the malignancy for at least five years.</li> <li>13. Have Symptomatic Cervical Disc Disease or significant cervical spondylosis at three (3) or more levels.</li> <li>14. Have marked cervical instability on resting (neutral) lateral or flexion-extension radiographs demonstrated by: <ol style="list-style-type: none"> <li>a. Translation <math>\geq 3.5</math> mm, and/or</li> <li>b. Greater than <math>11^\circ</math> angular difference to that of either adjacent level</li> </ol> </li> </ol>

Study Inclusion Criteria	Study Exclusion Criteria
	<ol style="list-style-type: none"> <li>15. Have known allergies to cobalt, chromium, molybdenum, titanium, nickel, or polyethylene.</li> <li>16. Are currently pregnant or breastfeeding at time of enrollment or have plans to become pregnant within the next three years.</li> <li>17. Have rheumatoid arthritis, lupus, or other autoimmune disease that affect the musculoskeletal system.</li> <li>18. Have congenital bony and/or spinal cord abnormalities that affect spinal stability.</li> <li>19. Have diseases or conditions that would preclude accurate clinical evaluation (e.g. neuromuscular disorders, uncontrolled fibromyalgia).</li> <li>20. Have concomitant conditions requiring daily, high-dose oral and/or inhaled steroids. High dose steroid use is defined as: <ol style="list-style-type: none"> <li>a. Daily, chronic use of oral steroids equivalent to 5 mg/day of prednisone or greater.</li> <li>b. Daily, chronic use of inhaled corticosteroids (at least twice per day).</li> <li>c. Use of short-term (less than 10 days) oral steroids at a daily dose greater than 40mg prednisone equivalent within one month of the study procedure.</li> </ol> </li> <li>21. Have current or recent history (defined <math>\leq 1</math> year prior to screening) of substance abuse (alcoholism and/or narcotic addiction) requiring intervention.</li> <li>22. Have a Body Mass Index (BMI) <math>&gt; 40</math> kg/m<sup>2</sup>.</li> <li>23. Using any other investigational drug or medical device within the last 30 days prior to surgery.</li> <li>24. Have evidence of symptomatic moderate to severe facet joint degeneration or disease where the investigator felt this was a major contributor to the subject's pain as diagnosed by injection and imaging.</li> <li>25. Taking medications known to potentially interfere with bone/soft tissue healing (e.g., high-dose oral and/or inhaled steroids, immunosuppressant medication, chemotherapeutic agents). High dose steroid use is defined as part of Exclusion Criterion #21.</li> <li>26. Have pending personal litigation relating to spinal injury (worker's compensation is not an exclusion).</li> <li>27. Have a current history of heavy smoking (more than one pack of cigarettes per day).</li> </ol>

Study Inclusion Criteria	Study Exclusion Criteria
	<ul style="list-style-type: none"> <li>28. Currently reside in a location, or anticipating a potential relocation, that may interfere with completion of follow-up examinations.</li> <li>29. Have mental illness or belonged to a vulnerable population, as determined by the investigator (e.g., prisoner or developmentally disabled), that would compromise ability to provide informed consent or compliance with follow-up requirements.</li> <li>30. Have an uncontrolled seizure disorder.</li> <li>31. Have had a cervical epidural steroid injection within 14 days prior to surgery</li> </ul>

2. Control

Control subjects were prospectively enrolled and randomized to treatment with the Mobi-C (N=140), a PMA-approved artificial cervical disc. The Mobi-C Cervical Disc was implanted according to its surgical technique guide.

3. Follow-Up Schedule

All subjects were evaluated pre-operatively, at treatment/discharge (prior to the subject being discharged from the hospital) and post-operatively at Week 6 ( $\pm 2$  weeks), Month 3 ( $\pm 2$  weeks), Month 6 ( $\pm 1$  month), Month 12 ( $\pm 2$  months), Month 24 ( $\pm 2$  months), Month 36 ( $\pm 2$  months) and annually thereafter ( $\pm 3$  months). The following parameters were measured throughout the study (**Figure 2**):

Procedures	Screening <sup>1</sup>	Surgery (Day 0)	Day 14 (+/- 7 days)	6 Wk (+/- 2 wks)	3 Mo (+/- 2 wks)	6 Mo (+/- 4 wks)	12 Mo (+/- 8 wks)	18 Mo <sup>6</sup> (+/- 8 wks)	24 Mo (+/- 8 wks)	36-84 Mos (+/- 8 wks)	Unscheduled
Informed Consent	X	-	-	-	-	-	-	-	-	-	-
Inclusion/Exclusion Criteria	X	X	-	-	-	-	-	-	-	-	-
Demographics	X	-	-	-	-	-	-	-	-	-	-
Medical History	X	-	-	-	-	-	-	-	-	-	-
Pregnancy Test	-	X	-	-	-	-	-	-	-	-	-
MRI or CAT Scan	X	-	-	-	-	-	-	-	-	-	-
DEXA Scan	X <sup>2</sup>	-	-	-	-	-	-	-	-	-	-
X-Ray	X	X <sup>5</sup>	X	X	X	X	X	-	X	X	X <sup>7</sup>
Assessments	X <sup>3,4</sup>	-	-	X <sup>3,4</sup>	X <sup>3,4</sup>	X <sup>3,4</sup>	X <sup>3,4</sup>	-	X <sup>3,4</sup>	X <sup>3,4</sup>	X <sup>3</sup>
Concomitant Medications	X	X	X	X	X	X	X	X	X	X	X <sup>7</sup>
Adverse Events	-	X	X	X	X	X	X	X	X	X	X <sup>7</sup>
Device Deficiencies	-	X	X	X	X	X	X	X	X	X	X <sup>7</sup>
Review Rehabilitation	-	X	X	X	X	X	X	-	X	-	X <sup>7</sup>

1. Screening may begin up to 60 days before surgery. Refer to Section 8.2 for the screening visit procedures that should be conducted before randomization occurs.  
2. DEXA required if the subject has a SCORE/MORES value  $\geq 6$ . A new DEXA is not required if the subject had a DEXA within the 24 months prior to the screening visit.  
3. Subject will complete Patient Reported Outcome questionnaires: VAS neck pain, VAS arm/shoulder pain, VAS hoarseness, Treatment Satisfaction (not at Screening), NDI Questionnaire, SF-12 Health Survey, and Dysphagia Handicap Index. These surveys should be administered prior to any other study visit assessments or procedures being performed.  
4. The Investigator/designee will complete the following assessments: a physical examination, the Nurick scale, Odom's Criteria (starting at the 6 Wk. visit), and a neurological assessment.  
5. Intraoperative AP and lateral radiographs/fluoroscopy should be taken prior to closure to verify proper implant positioning.  
6. The 18-month visit will be completed by telephone.  
7. The following procedures may be performed, if deemed necessary by the Investigator: Physical Examination, X-rays, Nurick Scale, Odom's Criteria Assessment, Neurological Assessment

**Figure 2: Clinical Study Schedule of Procedures**

#### 4. Clinical Endpoints

The safety of the prodisc® C SK and prodisc® C Vivo at two levels was assessed by comparison to the Mobi-C control group with respect to the nature and frequency of adverse events (overall and in terms of severity and relationship to the implant), subsequent index level surgical procedures, and maintenance or improvement in neurological status.

The effectiveness of the prodisc® C SK and prodisc® C Vivo at two levels was assessed by comparison to the Mobi-C control group with respect to a primary composite endpoint, as described below. Effectiveness was further evaluated by assessing improvement in the Neck Disability Index (NDI), neck and arm pain questionnaires, and quality of life using the short-form questionnaire (SF-12), as well as subject satisfaction of the prodisc® C SK and prodisc® C Vivo treatment as compared to the Mobi-C Cervical treatment. Similar criteria were used to measure success in both groups.

##### Primary Endpoint

The primary composite endpoint was defined as:

- 15-point improvement in NDI Score (out of 100) in subjects at the Month 24 timepoint compared with baseline;
- Maintenance or improvement in neurological status (motor and sensory only) at Month 24 compared to baseline;
- No secondary surgical interventions (revision, removal, re-operation, supplemental fixation) at the index level(s); and,
- Absence of major device-related adverse events (DRAEs) defined as radiographic failure, neurological failure, or failure by AE as adjudicated by the Clinical Events Committee (CEC).

For the purpose of determining individual subject success, the subject may not experience a major AE. A major AE was defined as any of the following which are definitely related to the device system or to a device component as determined by the CEC:

- No new or worsening permanent neurologic deficit;
- Implant or component breakage or migration that does not require revision, reoperation or removal, but causes persistent or moderate to severe dysphagia and/or,
- Subject death.

Subject success was evaluated using the primary composite endpoint above at Month 24. Study success was evaluated for the Month 24 Composite Clinical Success (CCS) using the following pre-specified hypotheses pertaining to clinical non-inferiority:

$H_0: \pi_T - \pi_C \leq -0.10$  (the CCS rate of investigational device was clinical inferior to control)

$H_a: \pi_T - \pi_C > -0.10$  (the CCS rate of investigational device was not clinical inferior to control)

where  $\pi_T$  and  $\pi_C$  are the probabilities of achieving Month 24 CCS of the investigational and control devices, respectively. In all circumstances, non-inferiority hypotheses were based on the *a priori* selected non-inferiority margin,  $\delta = -0.10$ .

The claim of non-inferiority was pre-specified to be accepted if the posterior probability of non-inferiority, is greater than or equal to 0.967. That is, if,  $\Pr(\pi_T - \pi_C > -\delta \mid \text{Trial Results}) \geq 0.967$ .

This posterior probability is calculated using Beta(1, 1) non-informative priors for both the investigational arm. A Bayesian posterior probability threshold of 0.967 controls type 1 error to 0.044 with statistical power of 84.6%.

Per FDA Guidance for the Preparation of IDEs for Spinal Systems (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-document-preparation-ides-spinal-systems-guidance-industry-andor-fda-staff>), the following definitions applied:

- Reoperation - any surgical procedure at the index level(s) that does not involve modification, addition, or removal of any components of the device in the post-operative or follow-up period.
- Revision – any procedure in the post-operative or follow-up period that adjusts, modifies, or removes part of the original implant configuration with or without replacement of a component – may include adjusting the position of the original configuration in the post-operative or follow-up period.
- Removal – a procedure where the entire device is removed with or without replacement of the device in the post-operative or follow-up period.
- Supplemental fixation – a procedure in which additional instrumentation not under study is implanted (e.g., supplemental placement of a plate/ screw fusion system).

### Secondary Endpoints

The Secondary endpoints measured in both groups included:

- Neck pain related disability as measured on a 100-point scale using the NDI questionnaire;
- Neck pain as measured on a 100mm Visual Analog Scale (VAS) at baseline and at each follow-up time-point;
- Worse arm/shoulder pain as measured separately on a 100mm VAS at baseline and at each follow-up time-point;
- VAS Hoarseness on a 100mm scale at baseline and at each follow-up time-point;
- Health Survey (SF-12v2) Physical Component Summary (PCS) at baseline and at each follow-up time-point (Results for MCS will be summarized);

- Treatment Satisfaction;
- Dysphagia Handicap Index (DHI) at Month 24 compared to baseline;
- Results at Month 24 for both treatment groups as categorized by the physician according to Odom's Criteria;
- Myelopathy based on the Nurick scale. A change of at least one grade at Month 24 compared to baseline will be regarded as clinically significant.

In addition to the above secondary endpoints, various neurologic and radiographic (quantitative and qualitative) assessments were measured and evaluated in both groups.

#### 5. Clinical Events Committee

A CEC was utilized for the prodisc® C SK and prodisc® C Vivo IDE study, including the Mobi-C Cervical Disc control group, to mitigate reporting bias of safety-related events. The CEC consisted of two spine surgeons and one neurosurgeon who are not affiliated with the sponsor and did not participate in the study. The CEC charter was used to define the role of the CEC. The recommendations of the CEC override the investigator's classification and become part of the clinical trial data set. The CEC adjudicated all AEs, secondary surgical interventions (SSIs), protocol deviations, and Month 24 neurological status.

AEs were reviewed to confirm or re-classify the AE term, severity, seriousness, anticipated versus unanticipated, and relationship to the investigational or control devices and/or the associated procedures. For events determined to be Serious, the CEC reviewed for the potential to re-classify the event as an Unanticipated Adverse Device Effect (UADE) or not a UADE. For the events determined to be definitely related to device, the CEC determined if they qualified as a 'Major' AE, per the primary endpoint. AEs which led to SSI were reviewed to determine if the SSI met the primary endpoint criteria for SSI failure and re-classify the event as reoperation, revision, removal or supplemental fixation. Protocol deviations were classified as 'major' or 'minor'. Lastly, the CEC adjudicated neurologic status at Month 24 for all subjects to determine if neurologic status was maintained, improved, or deteriorated relative to baseline.

#### **B. Accountability of PMA Cohort**

At the time of the December 31, 2024 database lock, a total of 480 subjects signed the informed consent form and were randomized (Intent-to-Treat Analysis Set):

- A total of **47** subjects were randomized, remained blinded, and ultimately not treated.
  - A total of **46** of the 47 subjects did not meet the eligibility criteria defined in Section 7.1 and Section 7.2 of the Protocol prior to treatment.
  - A total of **1** of the 47 subjects was not treated because they did not meet insurance requirements.

The resulting 433 available randomized subjects, with an operation date at the time of the database lock (293 prodisc® C SK and prodisc® C Vivo subjects and 140 Mobi-C control subjects) were assessed as part of the modified Intent-to-Treat (mITT) Analysis Set. Two subjects in the prodisc® C SK and prodisc® C Vivo group received fusion; therefore, the As-Treated (AT) Analysis Set includes 291 prodisc® C SK and prodisc® C Vivo subjects, and 140 Mobi-C subjects. There were

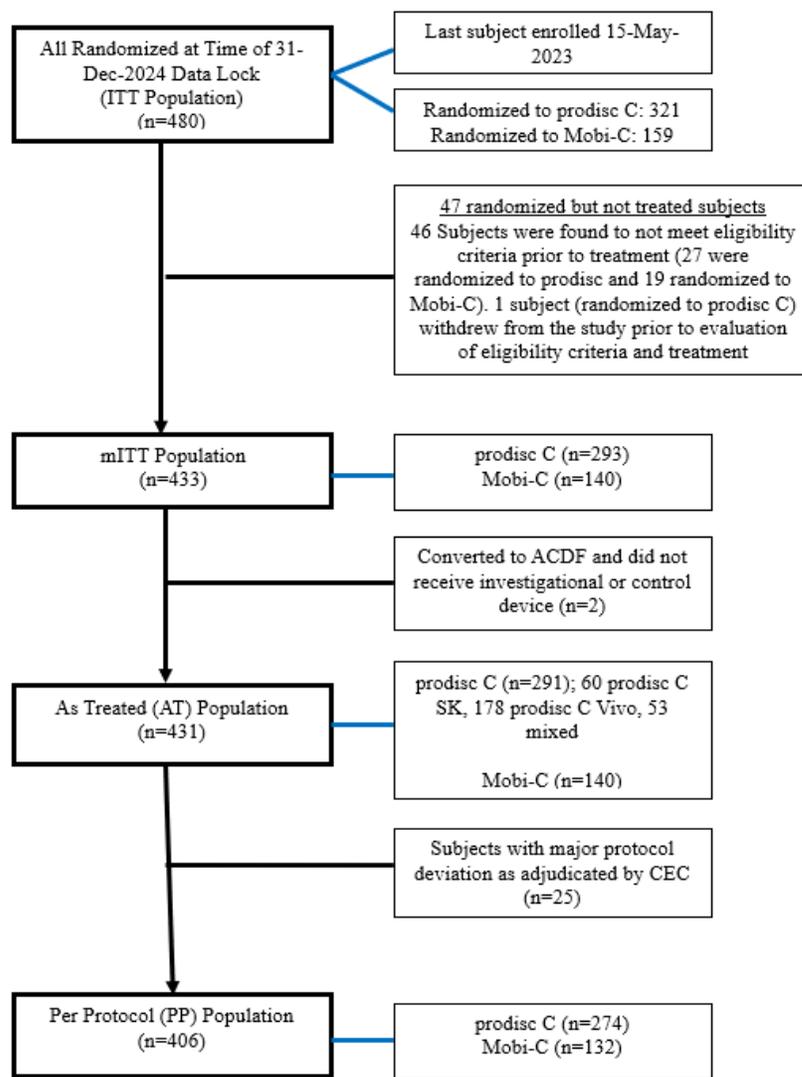
a total of 25 major protocol deviations, leaving the Per Protocol (PP) Analysis Set to include 406 subjects (274 prodisc® C SK and prodisc® C Vivo subjects, and 132 Mobi-C subjects). This information is presented in tabular form in **Table 4** below; similarly, this information is presented graphically via a patient accounting tree in **Figure 3** below.

**Table 4: Accounting Information**

	<b>prodisc® C SK and prodisc® C Vivo</b>	<b>Mobi-C</b>
<b>Randomized (ITT Analysis Set)</b>	321	159
<b>Subjects randomized but not treated*</b>	28	19
<b>mITT Analysis Set</b>	293	140
<b>As Treated (AT Analysis Set)</b>	291	140
<b>Number yet to reach 24 months (Day 730) as of database lock (mITT Analysis Set)</b>	16**	2
<b>Theoretical due (Day 730) as of database lock (mITT Analysis Set)</b>	277	138
<b>Subjects with known primary outcome (CCS) at the time of database lock (mITT Analysis Set)</b>	253	127
<b>Subjects with missing CCS outcome (mITT Set)</b>	<p><b>Subjects without CCS N=40</b></p> <ul style="list-style-type: none"> <li>• Not yet overdue (between 730 and 790) (N=5)</li> <li>• Below Day 730 (N=14)**</li> <li>• Missing for other reasons (N=21): <ul style="list-style-type: none"> <li>○ Lost to Follow-up (N=4)</li> <li>○ Death (N=2)</li> <li>○ Missed 24 Month Visit (N=10)</li> <li>○ Missing CCS Component (N=5)</li> </ul> </li> </ul>	<p><b>Subjects without CCS N=13</b></p> <ul style="list-style-type: none"> <li>• Not yet overdue (N=2)</li> <li>• Below Day 730 (N=2)</li> <li>• Missing for Other Reasons (N=9) <ul style="list-style-type: none"> <li>○ Withdrawn by investigator due to AE (N=1)</li> <li>○ Missed 24 Month Visit (N=3)</li> <li>○ Missing CCS Component (N=5)</li> </ul> </li> </ul>

\*This includes subjects who were randomized, but not treated because they did not meet eligibility criteria per Section 7.1 and 7.2 of the Protocol. One of these subjects was withdrawn because of an issue with insurance.

\*\*The difference between Number Yet to Reach Day 730 (N=16) and subjects Below Day 730 (N=14) is two subjects (06-039, 06-040) who had an SSI before Day 730, therefore they had a known CCS outcome, and are not a subject with a missing CCS.



**Figure 3: Subject Analysis Populations**

This submission includes data up to the database lock that occurred on December 31, 2024. The Month 24 CCS endpoint within the PP Analysis Set is based on 93% (342/367) of all subjects expected due. The Month 24 CCS endpoint for the mITT Analysis Set is based on 89% (348/392) of all subjects expected due. Within the mITT Analysis Set, 94.5% (277/293) of prodisc® C SK and prodisc® C Vivo subjects, and 98.6% (138/140) of Mobi-C subjects are theoretically due (Day 730); within this same analysis set, 91.3% (253/277) of prodisc® C SK and prodisc® C Vivo subjects, and 92.0% (127/138) of Mobi-C subjects have a known primary outcome.

The subject accountability summary through the Month 24 timepoint is presented in **Table 5** for the mITT Analysis Set. The accounting table is stratified by treatment arm with the overall prodisc® C SK and prodisc® C Vivo group subjects referred to hereafter as the investigational group (“I”), and Control group (“C”) for subjects that have completed follow up through Month 24.

**Table 5: Subject Accounting Summary (mITT Population, N=433) Through Month 24**

	Pre-Op		Treatment		Week 06		Month 03		Month 06		Month 12		Month 24	
	I	C	I	C	I	C	I	C	I	C	I	C	I	C
<b>Accounting</b>														
(1) Theoretical follow-up	293	140	293	140	293	140	293	140	293	140	293	140	277	138
(2) Cumulative Death			0	0	0	0	0	0	0	0	1	0	2	0
(3) Cumulative SSI Failures			0	0	1	0	1	1	2	3	4	4	9	6
(4) Not Yet Overdue			0	0	0	0	0	0	0	0	0	0	6	2
(5) Deaths+SSI failures among theoretically due			0	0	1	0	1	1	2	3	5	4	9	6
(6) Expected Due [(6)=(1)-(4)-(5)]					292	140	292	139	291	137	288	136	262	130
(7) SSI failures among theoretically due			0	0	1	0	1	1	2	3	4	4	7	6
(8) Expected due+SSI failures among theoretically due [(8)=(6)+(7)]					293	140	293	140	293	140	292	140	269	136
<b>All Evaluated Accounting (Actual<sup>B</sup>) Among Expected Due Procedures</b>														
(9) Procedures with any clinical data in interval†	293	140			272	134	279	135	280	136	277	130	243	121
(10) Visit Compliance (%)					93%	96%	96%	97%	96%	99%	96%	96%	93%	93%
(11) Change in NDI					272	134	279	135	280	136	277	130	243	121
(12) Composite Clinical Success (CCS)													243	121
(13) Actual <sup>B</sup> % Follow-up for CCS													93%	93%
<b>Within Window Accounting (Actual<sup>A</sup>) Among Expected Due Procedures</b>														
(14) Procedures with any clinical data in interval†	293	140			263	132	224	111	243	121	269	125	233	116
(15) Visit Compliance (%)					90%	94%	77%	80%	84%	88%	93%	92%	89%	89%
(16) Change in NDI					263	132	224	111	243	121	269	125	233	116
(17) Composite Clinical Success (CCS)													232	116
(18) Actual <sup>A</sup> % Follow-up for CCS													89%	89%
<sup>A</sup> Patients with complete data for each endpoint, within window. <sup>B</sup> Patients with any follow-up data reviewed or evaluated by investigator ("all evaluated" accounting). †Change in NDI; Source: Tables Follow-up Compliance mITT.sas; Analyzed: 31MAR2025														

### C. Study Population Demographics and Baseline Parameters

The tables below provide a summary of pre-operative and demographic variables for subjects treated in the study for both the investigational and control groups in the mITT Analysis Set. Variables summarized include age, BMI, height, and weight stratified by gender as well as race and ethnicity. Further, the demographics of the study population are typical for a cervical total disc replacement study performed in the United States. The proportions enrolled are consistent with the sex, age, racial and ethnicity of other cervical total disc replacement studies conducted to support a PMA with two-level indications in the US.

**Table 6: Pre-operative and Demographic Continuous Variables (mITT Analysis, N=433)**

	prodisc® C						Mobi-C						Group Difference*			
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	Δ	LB	UB	p
<b>All</b>																
Age (years)	293	49.4	8.8	50.0	22.6	69.5	140	48.7	9.1	47.9	29.1	69.0	0.7	-1.0	2.5	0.448
BMI (kg/m <sup>2</sup> )	292	29.2	4.8	29.2	17.7	40.6	140	28.4	4.5	28.2	18.5	39.8	0.9	0.0	1.8	0.069
Height (inches)	292	67.7	3.9	68.0	58.0	76.0	140	67.9	4.0	68.0	55.0	78.0	-0.2	-1.0	0.6	0.647
Weight (lbs)	292	191.5	37.9	190.0	103.0	275.0	140	186.8	36.8	182.3	118.0	284.0	4.7	-2.5	12.1	0.225
<b>Female</b>																
Age (years)	146	48.9	8.4	48.8	22.6	66.9	66	47.9	9.2	46.6	29.1	68.4	1.0	-1.3	3.6	0.422
BMI (kg/m <sup>2</sup> )	145	28.6	5.5	28.1	17.7	40.6	66	27.5	5.1	26.9	18.5	39.8	1.1	-0.4	2.6	0.194
Height (inches)	145	64.7	2.7	65.0	58.0	71.0	66	64.9	2.7	65.0	55.0	70.0	-0.1	-0.9	0.6	0.716
Weight (lbs)	145	170.0	33.3	167.6	103.0	270.0	66	164.4	30.6	159.5	118.0	239.0	5.6	-3.3	15.1	0.254
<b>Male</b>																
Age (years)	147	49.8	9.1	52.0	26.6	69.5	74	49.3	8.9	49.6	31.4	69.0	0.4	-2.0	2.9	0.740
BMI (kg/m <sup>2</sup> )	147	29.9	3.9	29.5	23.0	39.5	74	29.1	3.7	29.1	20.8	39.0	0.8	-0.2	1.9	0.143
Height (inches)	147	70.7	2.4	70.5	63.0	76.0	74	70.6	2.8	70.5	63.0	78.0	0.1	-0.6	0.8	0.861
Weight (lbs)	147	212.7	29.3	210.0	135.0	275.0	74	206.7	29.9	203.0	155.0	284.0	6.0	-1.8	14.2	0.156
<b>Clinical Scores</b>																
Neck Disability Index (NDI)	293	58.9	15.8	58.0	30.0	100.0	140	57.2	15.9	56.0	28.0	96.0	1.7	-1.3	4.8	0.305
VAS Back	293	73.8	18.7	77.0	2.0	100.0	140	74.3	17.4	77.0	0.0	100.0	-0.5	-4.0	3.1	0.786
VAS Hoarseness	293	19.0	25.9	5.0	0.0	100.0	140	19.5	27.2	4.0	0.0	100.0	-0.6	-5.6	4.7	0.827
VAS Left Arm/Shoulder	293	53.2	34.0	60.0	0.0	100.0	140	52.5	35.4	63.0	0.0	100.0	0.8	-5.8	7.6	0.828
VAS Right Arm/Shoulder	293	52.0	33.4	59.0	0.0	100.0	140	54.1	33.2	66.5	0.0	100.0	-2.0	-8.4	4.6	0.546
*Device group mean differences and 95% Credible Intervals. Nominal Two-sided t-test p-value (equal variance). Source: Tables Baseline Demo mITT.sas; Analyzed: 12MAR2025																

**Table 7: Pre-operative and Demographic Categorical Variables (mITT Analysis, N=433)**

	prodisc® C			Mobi-c			p*
	N	n	%	N	n	%	
<b>Race</b>							
Black or African American	293	17	5.8%	140	3	2.1%	0.242
Native Hawaiian or Other Pacific Islander		2	0.7%		0	0.0%	
Asian		1	0.3%		2	1.4%	
White		265	90.4%		131	93.6%	
Other		8	2.7%		4	2.9%	
<b>Ethnicity</b>							
Hispanic or Latino	293	14	4.8%	140	9	6.4%	0.496
Not Hispanic or Latino		279	95.2%		131	93.6%	
* Exact test p-value. Source: Tables Baseline Demo Categorical.sas; Analyzed: 2025-03-31							

The tables below provide a summary of intraoperative surgical variables for subjects treated in the study for both the investigational and control groups in the AT Analysis Set, and mITT Analysis Set. Variables summarized include operative time, blood loss, and length of stay. There was a difference in blood loss, in favor of Mobi-C. It is important to note that this difference is expected as Mobi-C does not require a keel cut during implantation. Furthermore, the keel cut into the

cancellous bone, which is required during implantation of prodisc® C SK, will create more bone bleeding than should be seen on average with prodisc® C Vivo or Mobi-C.

**Table 8: Summary of Continuous Intra-Operative Variables (mITT Analysis, N=433)**

	prodisc® C						Mobi-C						Group Difference*			
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	Δ	LB	UB	p
<b>All</b>																
Operative Time (minutes)	293	104.1	38.0	97.0	35.0	241.0	140	102.5	38.1	97.0	42.0	214.0	1.6	-5.7	9.1	0.697
Length of Stay (days)	293	0.5	0.8	0.0	0.0	9.0	140	0.5	0.6	0.5	0.0	4.0	0.0	-0.2	0.1	0.642
Blood Loss (cc)	293	33.6	30.5	25.0	5.0	200.0	140	26.7	17.9	25.0	5.0	100.0	7.0	1.8	12.3	0.013
*Device group mean differences and 95% Credible Intervals. Nominal Two-sided t-test p-value (equal variance). Source: Tables Intra-Op mITT.sas; Analyzed: 17MAR2025																

As demonstrated above, the investigational subjects and control subjects that make up the mITT analysis population are not significantly different with respect to baseline variables. Intra-operative data differed only for blood loss, with the control group reporting a lower mean amount (p = 0.013) than the investigational group.

#### **D. Study Results**

##### **1. Safety Results**

###### *Adverse Event Summary*

The CEC reviewed all safety events for both treatment groups, including AEs and SSIs, to allow for uniform adjudication of study-related events and evaluations and to eliminate any site-by-site variations in reporting. Specifically, the CEC reviewed and adjudicated AE category, severity, procedure and implant-relatedness, seriousness, and if serious, whether or not the event was anticipated.

**Table 9** shows a summary of AE categories and rates between the investigational and control groups in the ITT Analysis Set. Overall, similar rates of AEs occurred in the investigational group (78.5% - 252/321) and control group (78.6% - 125/159). SAEs that were considered “definitely” device-related were also comparable between the two groups, where 1.6% (5/321) of investigational subjects had “definitely” device-related SAEs, while 1.9% (3/159) control of subjects had “definitely” device-related SAEs. Lastly, the rate of SAEs that were considered “definitely” procedure-related was 3.1% (10/321) in investigational subjects and 1.9% (3/159) in control subjects.

**Table 9: Adverse Event Summary (ITT Analysis Set, N=480)**

	prodisc® C (N= 321)			Mobi-C (N= 159)			prodisc® C - Mobi-C			
	Events	n	%	Events	n	%	Δ	LB <sup>3</sup>	UB <sup>3</sup>	p-value <sup>4</sup>
<b>Adverse Events (AE)</b>										
All	832	252	78.5%	354	125	78.6%	-0.1%	-7.9%	7.7%	0.999
Device Related <sup>1</sup>	153	123	38.3%	82	65	40.9%	-2.6%	-11.9%	6.7%	0.620
Device Related - Definitely	9	8	2.5%	4	4	2.5%	0.0%	-3.0%	2.9%	0.999
Procedure Related <sup>2</sup>	252	158	49.2%	124	78	49.1%	0.2%	-9.3%	9.7%	0.999
Procedure Related - Definitely	41	35	10.9%	21	17	10.7%	0.2%	-5.7%	6.1%	0.999
<b>Serious Adverse Events (SAE)</b>										
All	72	60	18.7%	31	28	17.6%	1.1%	-6.2%	8.4%	0.803
Device Related <sup>1</sup>	10	9	2.8%	7	7	4.4%	-1.6%	-5.3%	2.1%	0.419
Device Related - Definitely	6	5	1.6%	3	3	1.9%	-0.3%	-2.8%	2.2%	0.724
Procedure Related <sup>2</sup>	19	17	5.3%	9	9	5.7%	-0.4%	-4.7%	4.0%	0.834
Procedure Related - Definitely	10	10	3.1%	3	3	1.9%	1.2%	-1.6%	4.1%	0.559
<b>AE by Severity</b>										
Mild	485	202	62.9%	204	90	56.6%	6.3%	-3.0%	15.7%	0.197
Moderate	261	137	42.7%	107	73	45.9%	-3.2%	-12.7%	6.2%	0.558
Severe	86	70	21.8%	43	36	22.6%	-0.8%	-8.8%	7.1%	0.907
<b>SAE by Severity</b>										
Mild	1	1	0.3%	1	1	0.6%	-0.3%	-1.7%	1.1%	0.553
Moderate	7	7	2.2%	6	6	3.8%	-1.6%	-5.0%	1.8%	0.372
Severe	64	54	16.8%	24	23	14.5%	2.4%	-4.5%	9.2%	0.597
<b>Death</b>										
All	2	2	0.6%	0	0	0.0%	0.6%	-0.2%	1.5%	0.999
NA=Not applicable. <sup>1</sup> Device related is anything that was possibly, probably or definitely related to the device. <sup>2</sup> Procedure related is anything that was possibly, probably or definitely related to the procedure. <sup>3</sup> 95% Exact unconditional confidence intervals. <sup>4</sup> Fisher's exact test. Source: Tables AE Summary ITT.sas; Analyzed: 01APR2025										

All Adverse Events

**Table 10** lists all AEs reported as of the database lock by AE term, with the number of subjects experiencing the events. Percentages are calculated as the number of subjects experiencing an event divided by the number of subjects treated in the ITT Analysis Set. The investigational group presented with 832 events occurring in 78.5% (252/321) of the 321 prodisc® subjects, compared to 354 events occurring in 78.6% (125/159) of the 125 Mobi-C control subjects.

The most common AEs (rate of 5% or more) included: dysphagia (investigational – 7.8%, 25/321; control – 8.8%, 14/159); general disorders and administrative site conditions – Covid-19 (investigational – 9.3%, 30/321; control – 8.2%, 13/159); joint pain (investigational – 11.5%, 37/321; control – 13.2%, 21/159); spasms (investigational – 7.5%, 24/321; control – 4.4%, 7/159); other musculoskeletal pain (investigational – 6.2%, 20/321; control – 6.9%, 11/159); numbness/tingling (investigational – 7.2%, 23/321; control – 5.7%, 9/159); radiculopathy (investigational – 21.5%, 69/321; control – 23.9%, 38/159); and trauma (investigational – 10.0%, 32/321; control – 11.9%, 19/159).

**Table 10: All Adverse Events (ITT Analysis Set N=480)**

	prodisc® C (N= 321)			Mobi C (N= 159)			Group Difference <sup>†</sup>		
	Events	Subjs	%*	Events	Subjs	%*	Δ	LB	UB
<b>All</b>	<b>832</b>	<b>252</b>	<b>78.5%</b>	<b>354</b>	<b>125</b>	<b>78.6%</b>	<b>-0.1%</b>	<b>-7.9%</b>	<b>7.7%</b>
<b>Blood and Lymphatic System Disorders</b>	<b>9</b>	<b>9</b>	<b>2.8%</b>	<b>2</b>	<b>2</b>	<b>1.3%</b>	<b>1.5%</b>	<b>-1.3%</b>	<b>4.4%</b>
Anemia	3	3	0.9%	1	1	0.6%	0.3%	-1.4%	2.0%
Blood Clots (non-pulmonary)	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Other Blood and Lymphatic System Disorders	5	5	1.6%	1	1	0.6%	0.9%	-1.2%	3.0%

	prodisc® C (N= 321)			Mobi C (N= 159)			Group Difference <sup>†</sup>		
	Events	Subjs	%*	Events	Subjs	%*	Δ	LB	UB
<b>Cardiac Disorders</b>	<b>8</b>	<b>8</b>	<b>2.5%</b>	<b>4</b>	<b>4</b>	<b>2.5%</b>	<b>0.0%</b>	<b>-3.0%</b>	<b>2.9%</b>
Acute Coronary Syndrome	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Atrial Fibrillation	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
Chest Pain	2	2	0.6%	1	1	0.6%	0.0%	-1.5%	1.5%
Myocardial Infarction	2	2	0.6%	0	0	0.0%	0.6%	-0.6%	1.8%
Syncope/Fainting	2	2	0.6%	1	1	0.6%	0.0%	-1.5%	1.5%
Ventricular Arrhythmia	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Other Cardiac Disorders	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
<b>Ear and Labyrinth Disorders</b>	<b>6</b>	<b>6</b>	<b>1.9%</b>	<b>3</b>	<b>2</b>	<b>1.3%</b>	<b>0.6%</b>	<b>-1.8%</b>	<b>3.0%</b>
Ear Pain	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Impaired Hearing	2	2	0.6%	0	0	0.0%	0.6%	-0.6%	1.8%
Vertigo	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Other Ear and Labyrinth Disorders	2	2	0.6%	3	2	1.3%	-0.6%	-2.4%	1.1%
<b>Endocrine Disorders</b>	<b>11</b>	<b>9</b>	<b>2.8%</b>	<b>4</b>	<b>3</b>	<b>1.9%</b>	<b>0.9%</b>	<b>-2.1%</b>	<b>3.9%</b>
Diabetes Mellitus	6	6	1.9%	1	1	0.6%	1.2%	-1.0%	3.5%
Hypothyroidism	2	2	0.6%	2	2	1.3%	-0.6%	-2.4%	1.1%
Hyperlipidemia	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Other Endocrine Disorder	2	2	0.6%	1	1	0.6%	0.0%	-1.5%	1.5%
<b>Eye Disorders</b>	<b>8</b>	<b>6</b>	<b>1.9%</b>	<b>2</b>	<b>2</b>	<b>1.3%</b>	<b>0.6%</b>	<b>-1.8%</b>	<b>3.0%</b>
Blurred Vision	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Cataract	3	2	0.6%	1	1	0.6%	0.0%	-1.5%	1.5%
Dry Eye	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Glaucoma	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Retinal Detachment	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
Other Eye Disorders	2	2	0.6%	0	0	0.0%	0.6%	-0.6%	1.8%
<b>Gastrointestinal Disorders</b>	<b>60</b>	<b>47</b>	<b>14.6%</b>	<b>32</b>	<b>26</b>	<b>16.4%</b>	<b>-1.7%</b>	<b>-8.5%</b>	<b>5.1%</b>
Constipation	1	1	0.3%	1	1	0.6%	-0.3%	-1.5%	0.9%
Diarrhea	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Dyspepsia	3	3	0.9%	1	1	0.6%	0.3%	-1.4%	2.0%
Dysphagia	26	25	7.8%	14	14	8.8%	-1.0%	-6.2%	4.2%
Gastroesophageal Reflux Disease	8	8	2.5%	1	1	0.6%	1.9%	-0.7%	4.4%
Hemorrhage	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
Hemorrhoids	2	2	0.6%	1	1	0.6%	0.0%	-1.5%	1.5%
Nausea	4	4	1.2%	1	1	0.6%	0.6%	-1.3%	2.5%
Vomiting	2	2	0.6%	3	3	1.9%	-1.3%	-3.2%	0.7%
Gastrointestinal Pain, Specify Location	2	2	0.6%	2	2	1.3%	-0.6%	-2.4%	1.1%
Pancreatitis	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
Ulcer, Specify Location	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Appendicitis	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
Other Gastrointestinal Disorder	10	10	3.1%	5	5	3.1%	0.0%	-3.3%	3.3%
<b>General Disorders and Administration</b>	<b>48</b>	<b>40</b>	<b>12.5%</b>	<b>15</b>	<b>13</b>	<b>8.2%</b>	<b>4.3%</b>	<b>-1.7%</b>	<b>10.2%</b>
Fatigue	3	3	0.9%	0	0	0.0%	0.9%	-0.6%	2.4%
Fever	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Flu-like symptoms	7	6	1.9%	1	1	0.6%	1.2%	-1.0%	3.5%
Gait Disturbance	2	2	0.6%	0	0	0.0%	0.6%	-0.6%	1.8%
General Pain, Not Specified Elsewhere	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
General Disorders and Administrative Site Conditions - COVID-19	33	30	9.3%	14	13	8.2%	1.2%	-4.3%	6.6%
Other General Disorders and Administrative Site Conditions	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%

	prodisc® C (N= 321)			Mobi C (N= 159)			Group Difference <sup>†</sup>		
	Events	Subjs	%*	Events	Subjs	%*	Δ	LB	UB
<b>Hepatobiliary Disorders</b>	<b>7</b>	<b>7</b>	<b>2.2%</b>	<b>0</b>	<b>0</b>	<b>0.0%</b>	<b>2.2%</b>	<b>-0.1%</b>	<b>4.5%</b>
Gallbladder Obstruction	2	2	0.6%	0	0	0.0%	0.6%	-0.6%	1.8%
Gallbladder Pain	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Other Hepatobiliary Disorders	4	4	1.2%	0	0	0.0%	1.2%	-0.5%	3.0%
<b>Immune System Disorders</b>	<b>10</b>	<b>9</b>	<b>2.8%</b>	<b>2</b>	<b>2</b>	<b>1.3%</b>	<b>1.5%</b>	<b>-1.3%</b>	<b>4.4%</b>
Allergic Reaction	7	6	1.9%	0	0	0.0%	1.9%	-0.2%	4.0%
Autoimmune Disorder	3	3	0.9%	2	2	1.3%	-0.3%	-2.3%	1.6%
<b>Infections and Infestations</b>	<b>35</b>	<b>31</b>	<b>9.7%</b>	<b>11</b>	<b>10</b>	<b>6.3%</b>	<b>3.4%</b>	<b>-1.9%</b>	<b>8.7%</b>
Infection, Surgical Site	6	6	1.9%	2	2	1.3%	0.6%	-1.8%	3.0%
Infection, Not at Surgical Site	13	13	4.0%	6	5	3.1%	0.9%	-2.7%	4.5%
Sinusitis	7	6	1.9%	0	0	0.0%	1.9%	-0.2%	4.0%
Rash	5	5	1.6%	1	1	0.6%	0.9%	-1.2%	3.0%
Sepsis	0	0	0.0%	2	2	1.3%	-1.3%	-2.5%	0.0%
Other Infections and Infestations	4	3	0.9%	0	0	0.0%	0.9%	-0.6%	2.4%
<b>Musculoskeletal and Connective Tissue Disorders</b>	<b>272</b>	<b>163</b>	<b>50.8%</b>	<b>122</b>	<b>76</b>	<b>47.8%</b>	<b>3.0%</b>	<b>-6.5%</b>	<b>12.5%</b>
Fracture, Any Bone	4	3	0.9%	1	1	0.6%	0.3%	-1.4%	2.0%
Joint Pain	40	37	11.5%	24	21	13.2%	-1.7%	-7.9%	4.5%
Joint Stiffness	4	4	1.2%	3	3	1.9%	-0.6%	-2.9%	1.6%
Ligament Injury	3	2	0.6%	0	0	0.0%	0.6%	-0.6%	1.8%
Muscle Weakness	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
Osteoarthritis	12	12	3.7%	4	4	2.5%	1.2%	-2.2%	4.6%
Spasms	26	24	7.5%	7	7	4.4%	3.1%	-1.6%	7.7%
Sprain	4	4	1.2%	2	2	1.3%	0.0%	-2.1%	2.1%
Other Musculoskeletal Pain, Specify Location	27	20	6.2%	11	11	6.9%	-0.7%	-5.4%	4.0%
Adjacent Segment Degeneration	7	7	2.2%	6	6	3.8%	-1.6%	-4.7%	1.5%
Lumbar Degenerative Disc Disease	5	5	1.6%	2	2	1.3%	0.3%	-2.0%	2.6%
Pseudarthrosis	1	1	0.3%	1	1	0.6%	-0.3%	-1.5%	0.9%
Cervical Pain	48	47	14.6%	21	19	11.9%	2.7%	-3.9%	9.2%
Lumbar Pain	27	25	7.8%	12	12	7.5%	0.2%	-4.8%	5.3%
Facet Joint Deterioration	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Spinal Stenosis	5	5	1.6%	0	0	0.0%	1.6%	-0.4%	3.5%
Spondylosis	2	2	0.6%	0	0	0.0%	0.6%	-0.6%	1.8%
Soft Tissue Injury/Inflammation	33	29	9.0%	17	14	8.8%	0.2%	-5.2%	5.7%
Thoracic Pain	5	5	1.6%	2	2	1.3%	0.3%	-2.0%	2.6%
Other Musculoskeletal and Connective Tissue Disorder	18	17	5.3%	8	8	5.0%	0.3%	-4.0%	4.5%
<b>Nervous System Disorders</b>	<b>178</b>	<b>121</b>	<b>37.7%</b>	<b>83</b>	<b>57</b>	<b>35.8%</b>	<b>1.8%</b>	<b>-7.3%</b>	<b>11.0%</b>
Amnesia	2	2	0.6%	0	0	0.0%	0.6%	-0.6%	1.8%
Central Nervous System Necrosis	3	3	0.9%	0	0	0.0%	0.9%	-0.6%	2.4%
Cognitive Disturbance	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
Dizziness	4	4	1.2%	1	1	0.6%	0.6%	-1.3%	2.5%
Dysesthesia	2	2	0.6%	1	1	0.6%	0.0%	-1.5%	1.5%
Dysphasia	2	2	0.6%	1	1	0.6%	0.0%	-1.5%	1.5%
Headache	15	13	4.0%	9	9	5.7%	-1.6%	-5.6%	2.4%
Neuralgia	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Neurological Deterioration (Motor, Sensory or Reflex)	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Numbness/Tingling	25	23	7.2%	12	9	5.7%	1.5%	-3.2%	6.2%
Paresthesia	0	0	0.0%	2	2	1.3%	-1.3%	-2.5%	0.0%
Peripheral Sensory Neuropathy	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Syncope	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Tremors	4	2	0.6%	0	0	0.0%	0.6%	-0.6%	1.8%
Compressive Neuropathy	28	24	7.5%	9	8	5.0%	2.4%	-2.3%	7.2%
Radiculopathy	79	69	21.5%	47	38	23.9%	-2.4%	-10.3%	5.5%
Weakness	3	3	0.9%	0	0	0.0%	0.9%	-0.6%	2.4%
Other Nervous System Disorder	7	7	2.2%	0	0	0.0%	2.2%	-0.1%	4.5%

	prodisc® C (N= 321)			Mobi C (N= 159)			Group Difference <sup>†</sup>		
	Events	Subjs	%*	Events	Subjs	%*	Δ	LB	UB
<b>Psychiatric Disorders</b>	<b>17</b>	<b>17</b>	<b>5.3%</b>	<b>11</b>	<b>10</b>	<b>6.3%</b>	<b>-1.0%</b>	<b>-5.4%</b>	<b>3.4%</b>
Anxiety Disorders	5	5	1.6%	6	6	3.8%	-2.2%	-5.1%	0.6%
Depression	6	6	1.9%	0	0	0.0%	1.9%	-0.2%	4.0%
Insomnia	4	4	1.2%	2	2	1.3%	0.0%	-2.1%	2.1%
Opioid Dependency	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
Other Psychiatric Disorder	2	2	0.6%	2	2	1.3%	-0.6%	-2.4%	1.1%
<b>Renal and Urinary Disorders</b>	<b>13</b>	<b>12</b>	<b>3.7%</b>	<b>5</b>	<b>5</b>	<b>3.1%</b>	<b>0.6%</b>	<b>-2.9%</b>	<b>4.1%</b>
Chronic Kidney Disease	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Renal Calculi	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Urinary incontinence	1	1	0.3%	1	1	0.6%	-0.3%	-1.5%	0.9%
Urinary Tract Infection	5	5	1.6%	1	1	0.6%	0.9%	-1.2%	3.0%
Other Renal and Urinary Disorder	5	5	1.6%	3	3	1.9%	-0.3%	-2.8%	2.1%
<b>Respiratory, Thoracic and Mediastinal Disorders</b>	<b>35</b>	<b>31</b>	<b>9.7%</b>	<b>6</b>	<b>6</b>	<b>3.8%</b>	<b>5.9%</b>	<b>0.8%</b>	<b>11.0%</b>
Allergic Rhinitis	2	2	0.6%	0	0	0.0%	0.6%	-0.6%	1.8%
Asthma	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Dyspnea	3	3	0.9%	0	0	0.0%	0.9%	-0.6%	2.4%
Hoarseness	8	7	2.2%	1	1	0.6%	1.6%	-0.9%	4.0%
Nasal Congestion	3	3	0.9%	1	1	0.6%	0.3%	-1.4%	2.0%
Pneumonia	5	5	1.6%	2	2	1.3%	0.3%	-2.0%	2.6%
Sleep Apnea	2	2	0.6%	0	0	0.0%	0.6%	-0.6%	1.8%
Sore Throat	3	3	0.9%	0	0	0.0%	0.9%	-0.6%	2.4%
Pulmonary Embolism	2	2	0.6%	0	0	0.0%	0.6%	-0.6%	1.8%
Airway Obstruction	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Sinusitis	2	2	0.6%	0	0	0.0%	0.6%	-0.6%	1.8%
Other Respiratory, Thoracic and Mediastinal Disorders Disorder	3	3	0.9%	2	2	1.3%	-0.3%	-2.3%	1.6%
<b>Skin and Subcutaneous Tissue Disorders</b>	<b>21</b>	<b>20</b>	<b>6.2%</b>	<b>8</b>	<b>7</b>	<b>4.4%</b>	<b>1.8%</b>	<b>-2.6%</b>	<b>6.2%</b>
Hematoma	5	5	1.6%	2	2	1.3%	0.3%	-2.0%	2.6%
Itching/Pruritus	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Seroma	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
Urticaria	2	2	0.6%	0	0	0.0%	0.6%	-0.6%	1.8%
Wound complications (eg., dehiscence, bruising) and soft tissue damage	3	3	0.9%	2	2	1.3%	-0.3%	-2.3%	1.6%
Wound secretions / drainage	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Other Skin and Subcutaneous Tissue Disorder	9	9	2.8%	3	3	1.9%	0.9%	-2.1%	3.9%
<b>Vascular Disorders</b>	<b>22</b>	<b>18</b>	<b>5.6%</b>	<b>6</b>	<b>6</b>	<b>3.8%</b>	<b>1.8%</b>	<b>-2.3%</b>	<b>6.0%</b>
Hemorrhage, Not Requiring Transfusion	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Hypertension	10	10	3.1%	5	5	3.1%	0.0%	-3.3%	3.3%
Neurovascular Injury	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Thromboembolic Event	2	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Vasculitis	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Other Vascular Disorder	7	7	2.2%	1	1	0.6%	1.6%	-0.9%	4.0%
<b>Device (non system specific)</b>	<b>11</b>	<b>10</b>	<b>3.1%</b>	<b>4</b>	<b>4</b>	<b>2.5%</b>	<b>0.6%</b>	<b>-2.6%</b>	<b>3.8%</b>
Implant Loosening	2	2	0.6%	0	0	0.0%	0.6%	-0.6%	1.8%
Implant Malalignment	1	1	0.3%	1	1	0.6%	-0.3%	-1.5%	0.9%
Implant Migration	6	6	1.9%	2	2	1.3%	0.6%	-1.8%	3.0%
Implant/Joint Noise	2	2	0.6%	1	1	0.6%	0.0%	-1.5%	1.5%
<b>Other Complications/Events</b>	<b>61</b>	<b>49</b>	<b>15.3%</b>	<b>34</b>	<b>28</b>	<b>17.6%</b>	<b>-2.3%</b>	<b>-9.3%</b>	<b>4.6%</b>
Surgery at a location other than the spine	7	7	2.2%	1	1	0.6%	1.6%	-0.9%	4.0%
Trauma	37	32	10.0%	24	19	11.9%	-2.0%	-7.8%	3.9%
Cancer	6	6	1.9%	3	3	1.9%	0.0%	-2.6%	2.6%
Adverse Reaction to Medication	3	3	0.9%	1	1	0.6%	0.3%	-1.4%	2.0%
Other Event, Describe	4	3	0.9%	2	2	1.3%	-0.3%	-2.3%	1.6%
Dental Disorder	1	1	0.3%	1	1	0.6%	-0.3%	-1.5%	0.9%
Other Gynecological Event	3	3	0.9%	2	2	1.3%	-0.3%	-2.3%	1.6%

\*Percentage of subjects experiencing specific event.  
†Normal approximation 95% Confidence Interval.  
Source: Tables Safety ITT.sas; Analyzed: 13MAR2025

*All Adverse Events Time course*

**Table 11** presents all AEs through Month 24 for both treatment groups. The time course interval where the highest number of AEs took place was between Month 12 and Month 24 for the investigational group, and between Month 6 and Month 12 for the control group.

**Table 1: All Adverse Events (Time Course) (ITT Analysis Set N=480)**

	Days Post-Op																			
	Missing		<0		0-2		2-30		30-90		90-180		180-365		365-730		730-790		Total	
	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C
<b>All</b>	17	12	0	0	44	16	80	30	79	48	107	43	140	84	240	80	125	41	832	354
<b>Blood and Lymphatic System Disorders</b>	0	0	0	0	0	0	3	0	0	0	0	0	2	1	3	1	1	0	9	2
Anemia	0	0	0	0	0	0	0	0	0	0	0	0	1	1	2	0	0	0	3	1
Blood Clots (non-pulmonary)	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1	0
Other Blood and Lymphatic System Disorders	0	0	0	0	0	0	2	0	0	0	0	0	1	0	1	1	1	0	5	1
<b>Cardiac Disorders</b>	0	0	0	0	0	0	1	0	0	0	0	0	3	2	3	2	1	0	8	4
Acute Coronary Syndrome	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1	0
Atrial Fibrillation	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1
Chest Pain	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	0	1	0	2	1
Myocardial Infarction	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0	0	0	2	0
Syncope/Fainting	0	0	0	0	0	0	1	0	0	0	0	0	1	0	0	1	0	0	2	1
Ventricular Arrhythmia	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0
Other Cardiac Disorders	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1
<b>Ear and Labyrinth Disorders</b>	1	0	0	0	1	0	0	0	0	0	0	1	2	0	0	0	2	2	6	3
Ear Pain	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0
Impaired Hearing	1	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	2	0
Vertigo	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1	0
Other Ear and Labyrinth Disorders	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	2	2	2	3
<b>Endocrine Disorders</b>	0	1	0	0	1	0	0	0	0	1	0	0	2	0	4	0	4	2	11	4
Diabetes Mellitus	0	1	0	0	0	0	0	0	0	0	0	0	1	0	2	0	3	0	6	1
Hypothyroidism	0	0	0	0	0	0	0	0	0	1	0	0	1	0	1	0	0	1	2	2
Hyperlipidemia	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0
Other Endocrine Disorder	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1	1	2	1
<b>Eye Disorders</b>	1	0	0	0	0	0	0	0	0	1	0	0	0	0	5	1	2	0	8	2
Blurred Vision	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0
Cataract	0	0	0	0	0	0	0	0	0	1	0	0	0	0	3	0	0	0	3	1
Dry Eye	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0
Glaucoma	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0
Retinal Detachment	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1
Other Eye Disorders	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	2	0

	Days Post-Op																			
	Missing		<0		0-2		2-30		30-90		90-180		180-365		365-730		730-790		Total	
	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C
<b>Gastrointestinal Disorders</b>	2	0	0	0	9	7	13	6	0	2	3	2	7	4	18	4	8	7	60	32
Constipation	0	0	0	0	0	0	0	0	0	0	0	1	0	0	1	0	0	0	1	1
Diarrhea	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1	0
Dyspepsia	0	0	0	0	0	1	0	0	0	0	0	0	2	0	1	0	0	0	3	1
Dysphagia	0	0	0	0	7	5	8	2	0	0	1	0	1	2	6	3	3	2	26	14
Gastroesophageal Reflux Disease	1	0	0	0	0	0	1	0	0	0	1	1	1	0	4	0	0	0	8	1
Hemorrhage	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1
Hemorrhoids	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	0	0	1	2	1
Nausea	1	0	0	0	1	0	0	0	0	0	0	0	0	1	1	0	1	0	4	1
Vomiting	0	0	0	0	0	1	1	0	0	0	1	0	0	1	0	0	0	1	2	3
Gastrointestinal Pain, Specify Location	0	0	0	0	0	0	0	1	0	1	0	0	1	0	0	0	1	0	2	2
Pancreatitis	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1
Ulcer, Specify Location	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0
Appendicitis	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1
Other Gastrointestinal Disorder	0	0	0	0	1	0	1	0	0	1	0	0	2	0	3	1	3	3	10	5
<b>General Disorders and Administration</b>	0	0	0	0	2	0	5	0	6	3	7	2	7	6	17	3	4	1	48	15
Fatigue	0	0	0	0	1	0	1	0	1	0	0	0	0	0	0	0	0	0	3	0
Fever	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0
Flu-like symptoms	0	0	0	0	0	0	1	0	1	0	0	0	2	0	3	0	0	1	7	1
Gait Disturbance	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	2	0
General Pain, Not Specified Elsewhere	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0
General Disorders and Administrative Site Conditions - COVID-19	0	0	0	0	0	0	1	0	4	3	7	2	5	6	13	3	3	0	33	14
Other General Disorders and Administrative Site Conditions	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0
<b>Hepatobiliary Disorders</b>	0	0	0	0	1	0	1	0	1	0	1	0	1	0	1	0	1	0	7	0
Gallbladder Obstruction	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	0	0	0	2	0
Gallbladder Pain	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0
Other Hepatobiliary Disorders	0	0	0	0	0	0	0	0	0	0	1	0	1	0	1	0	1	0	4	0
<b>Immune System Disorders</b>	1	0	0	0	1	0	2	0	0	0	1	0	2	0	1	2	2	0	10	2
Allergic Reaction	0	0	0	0	1	0	2	0	0	0	1	0	1	0	0	0	2	0	7	0
Autoimmune Disorder	1	0	0	0	0	0	0	0	0	0	0	0	1	0	1	2	0	0	3	2
<b>Infections and Infestations</b>	1	0	0	0	1	0	3	3	5	1	4	1	6	3	6	2	9	1	35	11
Infection, Surgical Site	0	0	0	0	0	0	3	1	1	1	1	0	0	0	1	0	0	0	6	2
Infection, Not at Surgical Site	1	0	0	0	1	0	0	1	3	0	2	1	3	3	2	1	1	0	13	6
Sinusitis	0	0	0	0	0	0	0	0	1	0	1	0	2	0	0	0	3	0	7	0
Rash	0	0	0	0	0	0	0	1	0	0	0	0	1	0	1	0	3	0	5	1
Sepsis	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0	2
Other Infections and Infestations	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	2	0	4	0

	Days Post-Op																			
	Missing		<0		0-2		2-30		30-90		90-180		180-365		365-730		730-790		Total	
	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C
<b>Musculoskeletal and Connective Tissue Disorders</b>	<b>5</b>	<b>5</b>	<b>0</b>	<b>0</b>	<b>10</b>	<b>4</b>	<b>20</b>	<b>13</b>	<b>26</b>	<b>13</b>	<b>34</b>	<b>11</b>	<b>45</b>	<b>29</b>	<b>83</b>	<b>30</b>	<b>49</b>	<b>17</b>	<b>272</b>	<b>122</b>
Fracture, Any Bone	1	0	0	0	1	0	0	0	1	0	0	0	0	0	0	1	1	0	4	1
Joint Pain	1	0	0	0	3	0	5	4	4	6	5	1	2	4	13	7	7	2	40	24
Joint Stiffness	0	0	0	0	0	0	2	0	0	0	0	1	1	0	1	2	0	0	4	3
Ligament Injury	0	0	0	0	0	0	0	0	1	0	1	0	0	0	1	0	0	0	3	0
Muscle Weakness	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1
Osteoarthritis	2	1	0	0	0	0	0	0	0	0	2	0	4	1	4	2	0	0	12	4
Spasms	0	0	0	0	3	1	2	0	4	0	6	2	2	3	6	0	3	1	26	7
Sprain	0	0	0	0	1	0	0	0	0	1	0	0	1	1	2	0	0	0	4	2
Other Musculoskeletal Pain, Specify Location	0	0	0	0	0	0	5	3	2	1	2	0	1	2	6	1	11	4	27	11
Adjacent Segment Degeneration	0	0	0	0	0	0	0	0	1	1	0	0	3	3	3	2	0	0	7	6
Lumbar Degenerative Disc Disease	1	0	0	0	0	0	0	0	1	0	1	0	1	2	1	0	0	0	5	2
Pseudarthrosis	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	0	0	1	1
Cervical Pain	0	0	0	0	0	2	5	2	3	3	5	3	15	3	12	3	8	5	48	21
Lumbar Pain	0	0	0	0	1	1	0	1	3	0	6	3	6	3	8	4	3	0	27	12
Facet Joint Deterioration	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0
Spinal Stenosis	0	0	0	0	0	0	0	0	0	0	1	0	1	0	1	0	2	0	5	0
Spondylosis	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1	0	0	0	2	0
Soft Tissue Injury/Inflammation	0	4	0	0	1	0	0	3	3	1	5	0	5	3	16	5	3	1	33	17
Thoracic Pain	0	0	0	0	0	0	0	0	2	0	0	0	1	2	2	0	0	0	5	2
Other Musculoskeletal and Connective Tissue Disorder	0	0	0	0	0	0	1	0	0	0	0	1	2	2	4	2	11	3	18	8
<b>Nervous System Disorders</b>	<b>3</b>	<b>2</b>	<b>0</b>	<b>0</b>	<b>6</b>	<b>2</b>	<b>14</b>	<b>7</b>	<b>23</b>	<b>12</b>	<b>33</b>	<b>16</b>	<b>39</b>	<b>21</b>	<b>41</b>	<b>19</b>	<b>19</b>	<b>4</b>	<b>178</b>	<b>83</b>
Amnesia	0	0	0	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	2	0
Central Nervous System Necrosis	0	0	0	0	0	0	0	0	2	0	0	0	1	0	0	0	0	0	3	0
Cognitive Disturbance	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1
Dizziness	0	0	0	0	1	0	1	0	1	0	0	1	0	0	1	0	0	0	4	1
Dysesthesia	0	0	0	0	2	0	0	1	0	0	0	0	0	0	0	0	0	0	2	1
Dysphasia	0	0	0	0	0	0	0	0	1	0	1	1	0	0	0	0	0	0	2	1
Headache	0	1	0	0	0	1	1	1	3	1	4	1	2	1	2	3	3	0	15	9
Neuralgia	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0
Neurological Deterioration (Motor, Sensory or Reflex)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0
Numbness/Tingling	1	0	0	0	0	0	3	0	3	4	2	1	9	3	5	3	2	1	25	12
Paresthesia	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	2
Peripheral Sensory Neuropathy	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0
Syncope	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0
Tremors	0	0	0	0	0	0	0	0	0	0	1	0	1	0	2	0	0	0	4	0
Compressive Neuropathy	0	1	0	0	0	0	0	0	5	0	7	5	4	1	9	2	3	0	28	9
Radiculopathy	2	0	0	0	3	1	9	5	7	7	17	7	19	13	13	11	9	3	79	47
Weakness	0	0	0	0	0	0	0	0	1	0	0	0	0	0	2	0	0	0	3	0
Other Nervous System Disorder	0	0	0	0	0	0	0	0	0	0	0	0	2	0	4	0	1	0	7	0

	Days Post-Op																			
	Missing		<0		0-2		2-30		30-90		90-180		180-365		365-730		730-790		Total	
	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C
<b>Psychiatric Disorders</b>	1	1	0	0	1	0	1	0	2	3	2	3	3	2	6	1	1	1	17	11
Anxiety Disorders	1	0	0	0	0	0	1	0	0	2	0	2	1	2	2	0	0	0	5	6
Depression	0	0	0	0	0	0	0	0	1	0	1	0	2	0	2	0	0	0	6	0
Insomnia	0	1	0	0	1	0	0	0	1	0	1	0	0	0	1	1	0	0	4	2
Opioid Dependency	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1
Other Psychiatric Disorder	0	0	0	0	0	0	0	0	0	0	0	1	0	0	1	0	1	1	2	2
<b>Renal and Urinary Disorders</b>	0	1	0	0	0	0	1	0	3	0	1	0	0	2	7	2	1	0	13	5
Chronic Kidney Disease	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0
Renal Calculi	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0
Urinary incontinence	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	0	1	1
Urinary Tract Infection	0	0	0	0	0	0	1	0	3	0	0	0	0	0	1	1	0	0	5	1
Other Renal and Urinary Disorder	0	1	0	0	0	0	0	0	0	0	1	0	0	2	4	0	0	0	5	3
<b>Respiratory, Thoracic and Mediastinal Disorders</b>	0	0	0	0	6	0	6	1	3	1	5	0	4	3	6	1	5	0	35	6
Allergic Rhinitis	0	0	0	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	2	0
Asthma	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0
Dyspnea	0	0	0	0	2	0	1	0	0	0	0	0	0	0	0	0	0	0	3	0
Hoarseness	0	0	0	0	3	0	1	0	1	1	1	0	0	0	2	0	0	0	8	1
Nasal Congestion	0	0	0	0	0	0	0	0	0	0	0	0	2	0	1	1	0	0	3	1
Pneumonia	0	0	0	0	1	0	1	0	0	0	1	0	0	2	2	0	0	0	5	2
Sleep Apnea	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0	2	0
Sore Throat	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3	0	3	0
Pulmonary Embolism	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	0	0	0	2	0
Airway Obstruction	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1	0
Sinusitis	0	0	0	0	0	0	1	0	0	0	1	0	0	0	0	0	0	0	2	0
Other Respiratory, Thoracic and Mediastinal Disorders Disorder	0	0	0	0	0	0	0	1	1	0	1	0	1	1	0	0	0	0	3	2
<b>Skin and Subcutaneous Tissue Disorders</b>	1	0	0	0	3	3	4	0	1	2	2	0	1	3	6	0	3	0	21	8
Hematoma	0	0	0	0	3	1	2	0	0	0	0	0	0	1	0	0	0	0	5	2
Itching/Pruritus	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0
Seroma	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1
Urticaria	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	2	0
Wound complications (eg., dehiscence, bruising) ar	0	0	0	0	0	1	2	0	0	1	0	0	0	0	0	0	1	0	3	2
Wound secretions / drainage	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1	0
Other Skin and Subcutaneous Tissue Disorder	1	0	0	0	0	1	0	0	0	0	0	0	1	2	5	0	2	0	9	3

	Days Post-Op																			
	Missing		<0		0-2		2-30		30-90		90-180		180-365		365-730		730-790		Total	
	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C
<b>Vascular Disorders</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>2</b>	<b>1</b>	<b>4</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>9</b>	<b>2</b>	<b>5</b>	<b>1</b>	<b>22</b>	<b>6</b>
Hemorrhage, Not Requiring Transfusion	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	0
Hypertension	0	0	0	0	1	0	0	0	2	1	2	0	0	1	3	2	2	1	10	5
Neurovascular Injury	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1	0
Thromboembolic Event	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	2	0
Vasculitis	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0
Other Vascular Disorder	0	1	0	0	0	0	0	0	0	0	1	0	0	0	4	0	2	0	7	1
<b>Device (non system specific)</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>3</b>	<b>2</b>	<b>3</b>	<b>0</b>	<b>3</b>	<b>1</b>	<b>1</b>	<b>0</b>	<b>11</b>	<b>4</b>
Implant Loosening	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0	2	0
Implant Malalignment	0	0	0	0	1	0	0	0	0	0	0	1	0	0	0	0	0	0	1	1
Implant Migration	0	0	0	0	0	0	0	0	0	1	2	1	2	0	2	0	0	0	6	2
Implant/Joint Noise	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	1	0	0	2	1
<b>Other Complications/Events</b>	<b>1</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>5</b>	<b>0</b>	<b>7</b>	<b>7</b>	<b>7</b>	<b>5</b>	<b>13</b>	<b>7</b>	<b>21</b>	<b>9</b>	<b>7</b>	<b>5</b>	<b>61</b>	<b>34</b>
Surgery at a location other than the spine	0	0	0	0	0	0	0	0	0	0	1	0	2	0	2	1	2	0	7	1
Trauma	0	0	0	0	0	0	3	0	6	3	6	5	9	7	11	6	2	3	37	24
Cancer	1	1	0	0	0	0	1	0	0	0	0	0	1	0	3	1	0	1	6	3
Adverse Reaction to Medication	0	0	0	0	0	0	1	0	1	0	0	0	0	0	1	1	0	0	3	1
Other Event, Describe	0	0	0	0	0	0	0	0	0	1	0	0	0	0	1	0	3	1	4	2
Dental Disorder	0	0	0	0	0	0	0	0	0	1	0	0	0	0	1	0	0	0	1	1
Other Gynecological Event	0	0	0	0	0	0	0	0	0	2	0	0	1	0	2	0	0	0	3	2

*All Adverse Events Severity*

**Table 12** presents the AEs observed in the investigational group stratified by severity. These AEs were classified as Mild, Moderate, or Severe events. Overall, there were 485 mild AEs, 261 moderate AEs, and 86 Severe AEs reported in the prodisc® C group in the ITT Analysis Set.

**Table 2: All Adverse Events (Severity)- prodisc® C Investigational (ITT Analysis Set N=321)**

	Mild		Moderate		Severe		Total
	Events	%*	Events	%*	Events	%*	Events
<b>All</b>	<b>485</b>	<b>58.3%</b>	<b>261</b>	<b>31.4%</b>	<b>86</b>	<b>10.3%</b>	<b>832</b>
<b>Blood and Lymphatic System Disorders</b>	<b>8</b>	<b>88.9%</b>	<b>1</b>	<b>11.1%</b>	<b>0</b>	<b>0.0%</b>	<b>9</b>
Anemia	2	66.7%	1	33.3%	0	0.0%	3
Blood Clots (non-pulmonary)	1	100.0%	0	0.0%	0	0.0%	1
Other Blood and Lymphatic System Disorders	5	100.0%	0	0.0%	0	0.0%	5
<b>Cardiac Disorders</b>	<b>5</b>	<b>62.5%</b>	<b>0</b>	<b>0.0%</b>	<b>3</b>	<b>37.5%</b>	<b>8</b>
Acute Coronary Syndrome	0	0.0%	0	0.0%	1	100.0%	1
Chest Pain	2	100.0%	0	0.0%	0	0.0%	2
Myocardial Infarction	0	0.0%	0	0.0%	2	100.0%	2
Syncope/Fainting	2	100.0%	0	0.0%	0	0.0%	2
Ventricular Arrhythmia	1	100.0%	0	0.0%	0	0.0%	1
<b>Ear and Labyrinth Disorders</b>	<b>3</b>	<b>50.0%</b>	<b>2</b>	<b>33.3%</b>	<b>1</b>	<b>16.7%</b>	<b>6</b>
Ear Pain	1	100.0%	0	0.0%	0	0.0%	1
Impaired Hearing	1	50.0%	1	50.0%	0	0.0%	2
Vertigo	0	0.0%	1	100.0%	0	0.0%	1
Other Ear and Labyrinth Disorders	1	50.0%	0	0.0%	1	50.0%	2
<b>Endocrine Disorders</b>	<b>9</b>	<b>81.8%</b>	<b>0</b>	<b>0.0%</b>	<b>2</b>	<b>18.2%</b>	<b>11</b>
Diabetes Mellitus	5	83.3%	0	0.0%	1	16.7%	6
Hypothyroidism	2	100.0%	0	0.0%	0	0.0%	2
Hyperlipidemia	1	100.0%	0	0.0%	0	0.0%	1
Other Endocrine Disorder	1	50.0%	0	0.0%	1	50.0%	2
<b>Eye Disorders</b>	<b>4</b>	<b>50.0%</b>	<b>4</b>	<b>50.0%</b>	<b>0</b>	<b>0.0%</b>	<b>8</b>
Blurred Vision	1	100.0%	0	0.0%	0	0.0%	1
Cataract	0	0.0%	3	100.0%	0	0.0%	3
Dry Eye	1	100.0%	0	0.0%	0	0.0%	1
Glaucoma	1	100.0%	0	0.0%	0	0.0%	1
Other Eye Disorders	1	50.0%	1	50.0%	0	0.0%	2
<b>Gastrointestinal Disorders</b>	<b>43</b>	<b>71.7%</b>	<b>13</b>	<b>21.7%</b>	<b>4</b>	<b>6.7%</b>	<b>60</b>
Constipation	0	0.0%	1	100.0%	0	0.0%	1
Diarrhea	1	100.0%	0	0.0%	0	0.0%	1
Dyspepsia	3	100.0%	0	0.0%	0	0.0%	3
Dysphagia	20	76.9%	6	23.1%	0	0.0%	26
Gastroesophageal Reflux Disease	6	75.0%	1	12.5%	1	12.5%	8
Hemorrhoids	2	100.0%	0	0.0%	0	0.0%	2
Nausea	4	100.0%	0	0.0%	0	0.0%	4
Vomiting	2	100.0%	0	0.0%	0	0.0%	2
Gastrointestinal Pain, Specify Location	0	0.0%	1	50.0%	1	50.0%	2
Ulcer, Specify Location	0	0.0%	1	100.0%	0	0.0%	1
Other Gastrointestinal Disorder	5	50.0%	3	30.0%	2	20.0%	10

	Mild		Moderate		Severe		Total
	Events	%*	Events	%*	Events	%*	Events
<b>General Disorders and Administration</b>	<b>45</b>	<b>93.8%</b>	<b>2</b>	<b>4.2%</b>	<b>1</b>	<b>2.1%</b>	<b>48</b>
Fatigue	3	100.0%	0	0.0%	0	0.0%	3
Fever	1	100.0%	0	0.0%	0	0.0%	1
Flu-like symptoms	6	85.7%	1	14.3%	0	0.0%	7
Gait Disturbance	2	100.0%	0	0.0%	0	0.0%	2
General Pain, Not Specified Elsewhere	1	100.0%	0	0.0%	0	0.0%	1
General Disorders and Administrative Site Conditions - COVID-19	31	93.9%	1	3.0%	1	3.0%	33
Other General Disorders and Administrative Site Conditions	1	100.0%	0	0.0%	0	0.0%	1
<b>Hepatobiliary Disorders</b>	<b>3</b>	<b>42.9%</b>	<b>1</b>	<b>14.3%</b>	<b>3</b>	<b>42.9%</b>	<b>7</b>
Gallbladder Obstruction	0	0.0%	1	50.0%	1	50.0%	2
Gallbladder Pain	0	0.0%	0	0.0%	1	100.0%	1
Other Hepatobiliary Disorders	3	75.0%	0	0.0%	1	25.0%	4
<b>Immune System Disorders</b>	<b>6</b>	<b>60.0%</b>	<b>4</b>	<b>40.0%</b>	<b>0</b>	<b>0.0%</b>	<b>10</b>
Allergic Reaction	5	71.4%	2	28.6%	0	0.0%	7
Autoimmune Disorder	1	33.3%	2	66.7%	0	0.0%	3
<b>Infections and Infestations</b>	<b>20</b>	<b>57.1%</b>	<b>10</b>	<b>28.6%</b>	<b>5</b>	<b>14.3%</b>	<b>35</b>
Infection, Surgical Site	3	50.0%	0	0.0%	3	50.0%	6
Infection, Not at Surgical Site	8	61.5%	4	30.8%	1	7.7%	13
Sinusitis	3	42.9%	4	57.1%	0	0.0%	7
Rash	5	100.0%	0	0.0%	0	0.0%	5
Other Infections and Infestations	1	25.0%	2	50.0%	1	25.0%	4
<b>Musculoskeletal and Connective Tissue Disorders</b>	<b>131</b>	<b>48.2%</b>	<b>117</b>	<b>43.0%</b>	<b>24</b>	<b>8.8%</b>	<b>272</b>
Fracture, Any Bone	2	50.0%	2	50.0%	0	0.0%	4
Joint Pain	24	60.0%	14	35.0%	2	5.0%	40
Joint Stiffness	1	25.0%	3	75.0%	0	0.0%	4
Ligament Injury	1	33.3%	2	66.7%	0	0.0%	3
Osteoarthritis	1	8.3%	7	58.3%	4	33.3%	12
Spasms	18	69.2%	8	30.8%	0	0.0%	26
Sprain	2	50.0%	2	50.0%	0	0.0%	4
Other Musculoskeletal Pain, Specify Location	18	66.7%	9	33.3%	0	0.0%	27
Adjacent Segment Degeneration	2	28.6%	4	57.1%	1	14.3%	7
Lumbar Degenerative Disc Disease	0	0.0%	1	20.0%	4	80.0%	5
Pseudarthrosis	0	0.0%	0	0.0%	1	100.0%	1
Cervical Pain	33	68.8%	14	29.2%	1	2.1%	48
Lumbar Pain	9	33.3%	15	55.6%	3	11.1%	27
Facet Joint Deterioration	1	100.0%	0	0.0%	0	0.0%	1
Spinal Stenosis	0	0.0%	3	60.0%	2	40.0%	5
Spondylosis	0	0.0%	1	50.0%	1	50.0%	2
Soft Tissue Injury/Inflammation	7	21.2%	22	66.7%	4	12.1%	33
Thoracic Pain	3	60.0%	2	40.0%	0	0.0%	5
Other Musculoskeletal and Connective Tissue Disorder	9	50.0%	8	44.4%	1	5.6%	18
<b>Nervous System Disorders</b>	<b>99</b>	<b>55.6%</b>	<b>71</b>	<b>39.9%</b>	<b>8</b>	<b>4.5%</b>	<b>178</b>
Amnesia	2	100.0%	0	0.0%	0	0.0%	2
Central Nervous System Necrosis	1	33.3%	2	66.7%	0	0.0%	3
Dizziness	4	100.0%	0	0.0%	0	0.0%	4
Dysesthesia	1	50.0%	1	50.0%	0	0.0%	2
Dysphasia	2	100.0%	0	0.0%	0	0.0%	2
Headache	11	73.3%	4	26.7%	0	0.0%	15
Neuralgia	1	100.0%	0	0.0%	0	0.0%	1
Neurological Deterioration (Motor, Sensory or Reflex)	0	0.0%	1	100.0%	0	0.0%	1
Numbness/Tingling	20	80.0%	5	20.0%	0	0.0%	25
Peripheral Sensory Neuropathy	0	0.0%	1	100.0%	0	0.0%	1
Syncope	1	100.0%	0	0.0%	0	0.0%	1
Tremors	4	100.0%	0	0.0%	0	0.0%	4
Compressive Neuropathy	20	71.4%	8	28.6%	0	0.0%	28
Radiculopathy	28	35.4%	44	55.7%	7	8.9%	79
Weakness	1	33.3%	2	66.7%	0	0.0%	3
Other Nervous System Disorder	3	42.9%	3	42.9%	1	14.3%	7

	Mild		Moderate		Severe		Total
	Events	%*	Events	%*	Events	%*	Events
<b>Psychiatric Disorders</b>	<b>12</b>	<b>70.6%</b>	<b>3</b>	<b>17.6%</b>	<b>2</b>	<b>11.8%</b>	<b>17</b>
Anxiety Disorders	3	60.0%	2	40.0%	0	0.0%	5
Depression	4	66.7%	1	16.7%	1	16.7%	6
Insomnia	4	100.0%	0	0.0%	0	0.0%	4
Other Psychiatric Disorder	1	50.0%	0	0.0%	1	50.0%	2
<b>Renal and Urinary Disorders</b>	<b>6</b>	<b>46.2%</b>	<b>5</b>	<b>38.5%</b>	<b>2</b>	<b>15.4%</b>	<b>13</b>
Chronic Kidney Disease	0	0.0%	1	100.0%	0	0.0%	1
Renal Calculi	0	0.0%	1	100.0%	0	0.0%	1
Urinary incontinence	0	0.0%	1	100.0%	0	0.0%	1
Urinary Tract Infection	3	60.0%	1	20.0%	1	20.0%	5
Other Renal and Urinary Disorder	3	60.0%	1	20.0%	1	20.0%	5
<b>Respiratory, Thoracic and Mediastinal Disorders</b>	<b>24</b>	<b>68.6%</b>	<b>7</b>	<b>20.0%</b>	<b>4</b>	<b>11.4%</b>	<b>35</b>
Allergic Rhinitis	1	50.0%	1	50.0%	0	0.0%	2
Asthma	1	100.0%	0	0.0%	0	0.0%	1
Dyspnea	2	66.7%	1	33.3%	0	0.0%	3
Hoarseness	8	100.0%	0	0.0%	0	0.0%	8
Nasal Congestion	3	100.0%	0	0.0%	0	0.0%	3
Pneumonia	1	20.0%	2	40.0%	2	40.0%	5
Sleep Apnea	2	100.0%	0	0.0%	0	0.0%	2
Sore Throat	3	100.0%	0	0.0%	0	0.0%	3
Pulmonary Embolism	0	0.0%	0	0.0%	2	100.0%	2
Airway Obstruction	0	0.0%	1	100.0%	0	0.0%	1
Sinusitis	2	100.0%	0	0.0%	0	0.0%	2
Other Respiratory, Thoracic and Mediastinal Disorders	1	33.3%	2	66.7%	0	0.0%	3
<b>Skin and Subcutaneous Tissue Disorders</b>	<b>16</b>	<b>76.2%</b>	<b>2</b>	<b>9.5%</b>	<b>3</b>	<b>14.3%</b>	<b>21</b>
Hematoma	3	60.0%	0	0.0%	2	40.0%	5
Itching/Pruritus	1	100.0%	0	0.0%	0	0.0%	1
Urticaria	1	50.0%	1	50.0%	0	0.0%	2
Wound complications (eg., dehiscence, bruising) and soft tissue damage	2	66.7%	0	0.0%	1	33.3%	3
Wound secretions / drainage	1	100.0%	0	0.0%	0	0.0%	1
Other Skin and Subcutaneous Tissue Disorder	8	88.9%	1	11.1%	0	0.0%	9
<b>Vascular Disorders</b>	<b>17</b>	<b>77.3%</b>	<b>2</b>	<b>9.1%</b>	<b>3</b>	<b>13.6%</b>	<b>22</b>
Hemorrhage, Not Requiring Transfusion	1	100.0%	0	0.0%	0	0.0%	1
Hypertension	9	90.0%	0	0.0%	1	10.0%	10
Neurovascular Injury	0	0.0%	0	0.0%	1	100.0%	1
Thromboembolic Event	0	0.0%	1	50.0%	1	50.0%	2
Vasculitis	0	0.0%	1	100.0%	0	0.0%	1
Other Vascular Disorder	7	100.0%	0	0.0%	0	0.0%	7
<b>Device (non system specific)</b>	<b>3</b>	<b>27.3%</b>	<b>2</b>	<b>18.2%</b>	<b>6</b>	<b>54.5%</b>	<b>11</b>
Implant Loosening	0	0.0%	0	0.0%	2	100.0%	2
Implant Malalignment	1	100.0%	0	0.0%	0	0.0%	1
Implant Migration	0	0.0%	2	33.3%	4	66.7%	6
Implant/Joint Noise	2	100.0%	0	0.0%	0	0.0%	2
<b>Other Complications/Events</b>	<b>31</b>	<b>50.8%</b>	<b>15</b>	<b>24.6%</b>	<b>15</b>	<b>24.6%</b>	<b>61</b>
Surgery at a location other than the spine	0	0.0%	2	28.6%	5	71.4%	7
Trauma	23	62.2%	11	29.7%	3	8.1%	37
Cancer	0	0.0%	0	0.0%	6	100.0%	6
Adverse Reaction to Medication	2	66.7%	1	33.3%	0	0.0%	3
Other Event, Describe	3	75.0%	0	0.0%	1	25.0%	4
Dental Disorder	0	0.0%	1	100.0%	0	0.0%	1
Other Gynecological Event	3	100.0%	0	0.0%	0	0.0%	3

**Table 13** presents the AEs observed in the control group stratified by severity. These AEs were classified as Mild, Moderate, or Severe events. Overall, there were 204 mild AEs, 107 moderate

AEs, and 43 Severe AEs reported in the control group. The most frequently occurring Severe AEs in the control group were joint pain (4 events) and adjacent segment degeneration (4 events).

**Table 3: All Adverse Events (Severity)- Mobi-C Control (ITT Analysis Set N=159)**

	Mild		Moderate		Severe		Total
	Events	%*	Events	%*	Events	%*	Events
<b>All</b>	<b>204</b>	<b>57.6%</b>	<b>107</b>	<b>30.2%</b>	<b>43</b>	<b>12.1%</b>	<b>354</b>
<b>Blood and Lymphatic System Disorders</b>	<b>1</b>	<b>50.0%</b>	<b>1</b>	<b>50.0%</b>	<b>0</b>	<b>0.0%</b>	<b>2</b>
Anemia	1	100.0%	0	0.0%	0	0.0%	1
Other Blood and Lymphatic System Disorders	0	0.0%	1	100.0%	0	0.0%	1
<b>Cardiac Disorders</b>	<b>1</b>	<b>25.0%</b>	<b>3</b>	<b>75.0%</b>	<b>0</b>	<b>0.0%</b>	<b>4</b>
Atrial Fibrillation	0	0.0%	1	100.0%	0	0.0%	1
Chest Pain	1	100.0%	0	0.0%	0	0.0%	1
Syncope/Fainting	0	0.0%	1	100.0%	0	0.0%	1
Other Cardiac Disorders	0	0.0%	1	100.0%	0	0.0%	1
<b>Ear and Labyrinth Disorders</b>	<b>1</b>	<b>33.3%</b>	<b>2</b>	<b>66.7%</b>	<b>0</b>	<b>0.0%</b>	<b>3</b>
Other Ear and Labyrinth Disorders	1	33.3%	2	66.7%	0	0.0%	3
<b>Endocrine Disorders</b>	<b>4</b>	<b>100.0%</b>	<b>0</b>	<b>0.0%</b>	<b>0</b>	<b>0.0%</b>	<b>4</b>
Diabetes Mellitus	1	100.0%	0	0.0%	0	0.0%	1
Hypothyroidism	2	100.0%	0	0.0%	0	0.0%	2
Other Endocrine Disorder	1	100.0%	0	0.0%	0	0.0%	1
<b>Eye Disorders</b>	<b>0</b>	<b>0.0%</b>	<b>1</b>	<b>50.0%</b>	<b>1</b>	<b>50.0%</b>	<b>2</b>
Cataract	0	0.0%	1	100.0%	0	0.0%	1
Retinal Detachment	0	0.0%	0	0.0%	1	100.0%	1
<b>Gastrointestinal Disorders</b>	<b>24</b>	<b>75.0%</b>	<b>7</b>	<b>21.9%</b>	<b>1</b>	<b>3.1%</b>	<b>32</b>
Constipation	1	100.0%	0	0.0%	0	0.0%	1
Dyspepsia	1	100.0%	0	0.0%	0	0.0%	1
Dysphagia	11	78.6%	3	21.4%	0	0.0%	14
Gastroesophageal Reflux Disease	1	100.0%	0	0.0%	0	0.0%	1
Hemorrhage	1	100.0%	0	0.0%	0	0.0%	1
Hemorrhoids	1	100.0%	0	0.0%	0	0.0%	1
Nausea	1	100.0%	0	0.0%	0	0.0%	1
Vomiting	2	66.7%	1	33.3%	0	0.0%	3
Gastrointestinal Pain, Specify Location	2	100.0%	0	0.0%	0	0.0%	2
Pancreatitis	0	0.0%	1	100.0%	0	0.0%	1
Appendicitis	0	0.0%	0	0.0%	1	100.0%	1
Other Gastrointestinal Disorder	3	60.0%	2	40.0%	0	0.0%	5
<b>General Disorders and Administration</b>	<b>15</b>	<b>100.0%</b>	<b>0</b>	<b>0.0%</b>	<b>0</b>	<b>0.0%</b>	<b>15</b>
Flu-like symptoms	1	100.0%	0	0.0%	0	0.0%	1
General Disorders and Administrative Site Conditions - COVID-19	14	100.0%	0	0.0%	0	0.0%	14
<b>Immune System Disorders</b>	<b>0</b>	<b>0.0%</b>	<b>2</b>	<b>100.0%</b>	<b>0</b>	<b>0.0%</b>	<b>2</b>
Autoimmune Disorder	0	0.0%	2	100.0%	0	0.0%	2
<b>Infections and Infestations</b>	<b>6</b>	<b>54.5%</b>	<b>2</b>	<b>18.2%</b>	<b>3</b>	<b>27.3%</b>	<b>11</b>
Infection, Surgical Site	2	100.0%	0	0.0%	0	0.0%	2
Infection, Not at Surgical Site	3	50.0%	2	33.3%	1	16.7%	6
Rash	1	100.0%	0	0.0%	0	0.0%	1
Sepsis	0	0.0%	0	0.0%	2	100.0%	2

	Mild		Moderate		Severe		Total
	Events	%*	Events	%*	Events	%*	Events
<b>Musculoskeletal and Connective Tissue Disorders</b>	<b>69</b>	<b>56.6%</b>	<b>34</b>	<b>27.9%</b>	<b>19</b>	<b>15.6%</b>	<b>122</b>
Fracture, Any Bone	0	0.0%	1	100.0%	0	0.0%	1
Joint Pain	14	58.3%	6	25.0%	4	16.7%	24
Joint Stiffness	2	66.7%	1	33.3%	0	0.0%	3
Muscle Weakness	0	0.0%	1	100.0%	0	0.0%	1
Osteoarthritis	0	0.0%	1	25.0%	3	75.0%	4
Spasms	5	71.4%	2	28.6%	0	0.0%	7
Sprain	2	100.0%	0	0.0%	0	0.0%	2
Other Musculoskeletal Pain, Specify Location	7	63.6%	4	36.4%	0	0.0%	11
Adjacent Segment Degeneration	1	16.7%	1	16.7%	4	66.7%	6
Lumbar Degenerative Disc Disease	0	0.0%	1	50.0%	1	50.0%	2
Pseudarthrosis	0	0.0%	1	100.0%	0	0.0%	1
Cervical Pain	15	71.4%	5	23.8%	1	4.8%	21
Lumbar Pain	9	75.0%	1	8.3%	2	16.7%	12
Soft Tissue Injury/Inflammation	6	35.3%	8	47.1%	3	17.6%	17
Thoracic Pain	2	100.0%	0	0.0%	0	0.0%	2
Other Musculoskeletal and Connective Tissue Disorder	6	75.0%	1	12.5%	1	12.5%	8
<b>Nervous System Disorders</b>	<b>44</b>	<b>53.0%</b>	<b>30</b>	<b>36.1%</b>	<b>9</b>	<b>10.8%</b>	<b>83</b>
Cognitive Disturbance	0	0.0%	1	100.0%	0	0.0%	1
Dizziness	1	100.0%	0	0.0%	0	0.0%	1
Dysesthesia	0	0.0%	1	100.0%	0	0.0%	1
Dysphasia	1	100.0%	0	0.0%	0	0.0%	1
Headache	7	77.8%	2	22.2%	0	0.0%	9
Numbness/Tingling	11	91.7%	1	8.3%	0	0.0%	12
Paresthesia	1	50.0%	1	50.0%	0	0.0%	2
Compressive Neuropathy	4	44.4%	3	33.3%	2	22.2%	9
Radiculopathy	19	40.4%	21	44.7%	7	14.9%	47
<b>Psychiatric Disorders</b>	<b>7</b>	<b>63.6%</b>	<b>4</b>	<b>36.4%</b>	<b>0</b>	<b>0.0%</b>	<b>11</b>
Anxiety Disorders	5	83.3%	1	16.7%	0	0.0%	6
Insomnia	1	50.0%	1	50.0%	0	0.0%	2
Opioid Dependency	0	0.0%	1	100.0%	0	0.0%	1
Other Psychiatric Disorder	1	50.0%	1	50.0%	0	0.0%	2
<b>Renal and Urinary Disorders</b>	<b>4</b>	<b>80.0%</b>	<b>1</b>	<b>20.0%</b>	<b>0</b>	<b>0.0%</b>	<b>5</b>
Urinary incontinence	1	100.0%	0	0.0%	0	0.0%	1
Urinary Tract Infection	1	100.0%	0	0.0%	0	0.0%	1
Other Renal and Urinary Disorder	2	66.7%	1	33.3%	0	0.0%	3
<b>Respiratory, Thoracic and Mediastinal Disorders</b>	<b>1</b>	<b>16.7%</b>	<b>5</b>	<b>83.3%</b>	<b>0</b>	<b>0.0%</b>	<b>6</b>
Hoarseness	0	0.0%	1	100.0%	0	0.0%	1
Nasal Congestion	0	0.0%	1	100.0%	0	0.0%	1
Pneumonia	0	0.0%	2	100.0%	0	0.0%	2
Other Respiratory, Thoracic and Medistinal Disorders	1	50.0%	1	50.0%	0	0.0%	2
<b>Skin and Subcutaneous Tissue Disorders</b>	<b>3</b>	<b>37.5%</b>	<b>4</b>	<b>50.0%</b>	<b>1</b>	<b>12.5%</b>	<b>8</b>
Hematoma	1	50.0%	1	50.0%	0	0.0%	2
Seroma	0	0.0%	1	100.0%	0	0.0%	1
Wound complications (eg., dehiscence, bruising) and soft tissue damage	2	100.0%	0	0.0%	0	0.0%	2
Other Skin and Subcutaneous Tissue Disorder	0	0.0%	2	66.7%	1	33.3%	3

	Mild		Moderate		Severe		Total
	Events	%*	Events	%*	Events	%*	Events
<b>Vascular Disorders</b>	<b>5</b>	<b>83.3%</b>	<b>1</b>	<b>16.7%</b>	<b>0</b>	<b>0.0%</b>	<b>6</b>
Hypertension	4	80.0%	1	20.0%	0	0.0%	5
Other Vascular Disorder	1	100.0%	0	0.0%	0	0.0%	1
<b>Device (non system specific)</b>	<b>1</b>	<b>25.0%</b>	<b>0</b>	<b>0.0%</b>	<b>3</b>	<b>75.0%</b>	<b>4</b>
Implant Malalignment	0	0.0%	0	0.0%	1	100.0%	1
Implant Migration	0	0.0%	0	0.0%	2	100.0%	2
Implant/Joint Noise	1	100.0%	0	0.0%	0	0.0%	1
<b>Other Complications/Events</b>	<b>18</b>	<b>52.9%</b>	<b>10</b>	<b>29.4%</b>	<b>6</b>	<b>17.6%</b>	<b>34</b>
Surgery at a location other than the spine	0	0.0%	0	0.0%	1	100.0%	1
Trauma	12	50.0%	9	37.5%	3	12.5%	24
Cancer	1	33.3%	0	0.0%	2	66.7%	3
Adverse Reaction to Medication	1	100.0%	0	0.0%	0	0.0%	1
Other Event, Describe	2	100.0%	0	0.0%	0	0.0%	2
Dental Disorder	1	100.0%	0	0.0%	0	0.0%	1
Other Gynecological Event	1	50.0%	1	50.0%	0	0.0%	2

### Device-Related Adverse Events

**Table 14** presents all device-related AEs recorded in the ITT Analysis Set. Overall, the investigational group presented with 153 device-related AEs in 38.3% (123/321) of the 321 prodisc® subjects, compared to 82 device-related AEs in 40.9% (65/159) of the 159 Mobi-C subjects.

The most common device-related AEs included cervical pain (investigational – 12.1%, 39/321; control – 9.4%, 15/159), spasms (investigational – 5.3%, 17/321; control – 2.5%, 4/159), and radiculopathy (investigational – 14.3%, 46/321; control – 17.6%, 28/159).

The majority of device-related AE occurred between Month 6 and Month 12 for both groups. In the investigational group, the most frequently occurring device-related AEs classified as Severe were implant migration (n=4 events), implant loosening (n=2 events), and radiculopathy (n=2 events). In the control group, the most frequently occurring device-related AEs classified as Severe were adjacent segment degeneration (n=4 events), radiculopathy (n=3 events), and implant migration (n=2 events).

**Table 14: All Device- Related Adverse Events (ITT Analysis Set N=480)**

	prodisc® C (N= 321)			Mobi C (N= 159)			Group Difference <sup>†</sup>		
	Events	Subjs	%*	Events	Subjs	%*	Δ	LB	UB
<b>All</b>	<b>153</b>	<b>123</b>	<b>38.3%</b>	<b>82</b>	<b>65</b>	<b>40.9%</b>	<b>-2.6%</b>	<b>-11.8%</b>	<b>6.7%</b>
<b>Ear and Labyrinth Disorders</b>	<b>0</b>	<b>0</b>	<b>0.0%</b>	<b>1</b>	<b>1</b>	<b>0.6%</b>	<b>-0.6%</b>	<b>-1.5%</b>	<b>0.2%</b>
Other Ear and Labyrinth Disorders	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
<b>Gastrointestinal Disorders</b>	<b>2</b>	<b>2</b>	<b>0.6%</b>	<b>1</b>	<b>1</b>	<b>0.6%</b>	<b>0.0%</b>	<b>-1.5%</b>	<b>1.5%</b>
Dysphagia	2	2	0.6%	1	1	0.6%	0.0%	-1.5%	1.5%
<b>Infections and Infestations</b>	<b>1</b>	<b>1</b>	<b>0.3%</b>	<b>0</b>	<b>0</b>	<b>0.0%</b>	<b>0.3%</b>	<b>-0.6%</b>	<b>1.2%</b>
Infection, Surgical Site	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
<b>Musculoskeletal and Connective Tissue Disorders</b>	<b>72</b>	<b>66</b>	<b>20.6%</b>	<b>35</b>	<b>32</b>	<b>20.1%</b>	<b>0.4%</b>	<b>-7.2%</b>	<b>8.1%</b>
Joint Pain	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
Joint Stiffness	1	1	0.3%	1	1	0.6%	-0.3%	-1.5%	0.9%
Muscle Weakness	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
Osteoarthritis	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Spasms	18	17	5.3%	4	4	2.5%	2.8%	-1.1%	6.7%
Sprain	1	1	0.3%	1	1	0.6%	-0.3%	-1.5%	0.9%
Other Musculoskeletal Pain, Specify Location	4	4	1.2%	3	3	1.9%	-0.6%	-2.9%	1.6%
Adjacent Segment Degeneration	7	7	2.2%	6	6	3.8%	-1.6%	-4.7%	1.5%
Cervical Pain	39	39	12.1%	16	15	9.4%	2.7%	-3.3%	8.7%
Facet Joint Deterioration	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Other Musculoskeletal and Connective Tissue Disorder	0	0	0.0%	2	2	1.3%	-1.3%	-2.5%	0.0%
<b>Nervous System Disorders</b>	<b>67</b>	<b>59</b>	<b>18.4%</b>	<b>39</b>	<b>36</b>	<b>22.6%</b>	<b>-4.3%</b>	<b>-11.8%</b>	<b>3.3%</b>
Dysesthesia	2	2	0.6%	1	1	0.6%	0.0%	-1.5%	1.5%
Headache	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
Numbness/Tingling	13	12	3.7%	4	4	2.5%	1.2%	-2.2%	4.6%
Paresthesia	0	0	0.0%	2	2	1.3%	-1.3%	-2.5%	0.0%
Radiculopathy	49	46	14.3%	31	28	17.6%	-3.3%	-10.1%	3.6%
Weakness	2	2	0.6%	0	0	0.0%	0.6%	-0.6%	1.8%
Other Nervous System Disorder	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
<b>Device (non system specific)</b>	<b>11</b>	<b>10</b>	<b>3.1%</b>	<b>4</b>	<b>4</b>	<b>2.5%</b>	<b>0.6%</b>	<b>-2.6%</b>	<b>3.8%</b>
Implant Loosening	2	2	0.6%	0	0	0.0%	0.6%	-0.6%	1.8%
Implant Malalignment	1	1	0.3%	1	1	0.6%	-0.3%	-1.5%	0.9%
Implant Migration	6	6	1.9%	2	2	1.3%	0.6%	-1.8%	3.0%
Implant/Joint Noise	2	2	0.6%	1	1	0.6%	0.0%	-1.5%	1.5%
<b>Other Complications/Events</b>	<b>0</b>	<b>0</b>	<b>0.0%</b>	<b>2</b>	<b>2</b>	<b>1.3%</b>	<b>-1.3%</b>	<b>-2.5%</b>	<b>0.0%</b>
Trauma	0	0	0.0%	2	2	1.3%	-1.3%	-2.5%	0.0%

*Procedure-Related Adverse Events*

**Table 15** presents all procedure-related AEs recorded in the ITT Analysis Set. Overall, there were 252 procedure-related AEs in 49.2% (158/321) of the 321 prodisc® subjects, compared to 124 procedure-related AEs in 49.1% (78/159) of the 159 Mobi-C subjects.

The most common procedure-related AEs included: dysphagia (investigational – 7.2%, 23/321; control – 6.3%, 10/159); spasms (investigational – 5.9%, 19/321; control – 3.8%, 6/159); and radiculopathy (investigational – 15%, 48/321; control – 18.9%, 30/159).

The majority of procedure-related AEs occurred between 0 and 30 days post-operatively for both groups. In the investigational group, the most frequently occurring procedure-related AEs classified as Severe were implant migration (n=4 events), implant loosening (n=2 events), and radiculopathy (n=2 events), hematoma (n=2 events), and surgical site infection (n=2 events). In the control group, the most frequently occurring device-related AEs classified as Severe were adjacent segment degeneration (n=4 events), radiculopathy (n=3 events), and implant migration (n=2 events).

**Table 15: All Procedure- Related Adverse Events (ITT Analysis Set N= 480)**

	prodisc® C (N= 321)			Mobi C (N= 159)			Group Difference <sup>†</sup>		
	Events	Subjs	%*	Events	Subjs	%*	Δ	LB	UB
<b>All</b>	<b>252</b>	<b>158</b>	<b>49.2%</b>	<b>124</b>	<b>78</b>	<b>49.1%</b>	<b>0.2%</b>	<b>-9.3%</b>	<b>9.7%</b>
<b>Blood and Lymphatic System Disorders</b>	<b>2</b>	<b>2</b>	<b>0.6%</b>	<b>0</b>	<b>0</b>	<b>0.0%</b>	<b>0.6%</b>	<b>-0.6%</b>	<b>1.8%</b>
Blood Clots (non-pulmonary)	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Other Blood and Lymphatic System Disorders	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
<b>Ear and Labyrinth Disorders</b>	<b>1</b>	<b>1</b>	<b>0.3%</b>	<b>1</b>	<b>1</b>	<b>0.6%</b>	<b>-0.3%</b>	<b>-1.5%</b>	<b>0.9%</b>
Ear Pain	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Other Ear and Labyrinth Disorders	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%

	prodisc® C (N= 321)			Mobi C (N= 159)			Group Difference <sup>†</sup>		
	Events	Subjs	%*	Events	Subjs	%*	Δ	LB	UB
<b>Gastrointestinal Disorders</b>	<b>30</b>	<b>28</b>	<b>8.7%</b>	<b>15</b>	<b>12</b>	<b>7.5%</b>	<b>1.2%</b>	<b>-4.1%</b>	<b>6.4%</b>
Diarrhea	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Dyspepsia	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
Dysphagia	24	23	7.2%	10	10	6.3%	0.9%	-3.9%	5.7%
Gastroesophageal Reflux Disease	2	2	0.6%	0	0	0.0%	0.6%	-0.6%	1.8%
Hemorrhage	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
Nausea	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Vomiting	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
Gastrointestinal Pain, Specify Location	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
Pancreatitis	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
Other Gastrointestinal Disorder	2	2	0.6%	0	0	0.0%	0.6%	-0.6%	1.8%
<b>General Disorders and Administration</b>	<b>3</b>	<b>3</b>	<b>0.9%</b>	<b>0</b>	<b>0</b>	<b>0.0%</b>	<b>0.9%</b>	<b>-0.6%</b>	<b>2.4%</b>
Fatigue	2	2	0.6%	0	0	0.0%	0.6%	-0.6%	1.8%
Fever	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
<b>Hepatobiliary Disorders</b>	<b>1</b>	<b>1</b>	<b>0.3%</b>	<b>0</b>	<b>0</b>	<b>0.0%</b>	<b>0.3%</b>	<b>-0.6%</b>	<b>1.2%</b>
Gallbladder Obstruction	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
<b>Immune System Disorders</b>	<b>2</b>	<b>2</b>	<b>0.6%</b>	<b>0</b>	<b>0</b>	<b>0.0%</b>	<b>0.6%</b>	<b>-0.6%</b>	<b>1.8%</b>
Allergic Reaction	2	2	0.6%	0	0	0.0%	0.6%	-0.6%	1.8%
<b>Infections and Infestations</b>	<b>5</b>	<b>5</b>	<b>1.6%</b>	<b>4</b>	<b>4</b>	<b>2.5%</b>	<b>-1.0%</b>	<b>-3.5%</b>	<b>1.6%</b>
Infection, Surgical Site	5	5	1.6%	2	2	1.3%	0.3%	-2.0%	2.6%
Infection, Not at Surgical Site	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
Rash	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
<b>Musculoskeletal and Connective Tissue Disorders</b>	<b>92</b>	<b>80</b>	<b>24.9%</b>	<b>46</b>	<b>36</b>	<b>22.6%</b>	<b>2.3%</b>	<b>-5.9%</b>	<b>10.4%</b>
Fracture, Any Bone	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Joint Pain	7	7	2.2%	3	3	1.9%	0.3%	-2.4%	3.0%
Joint Stiffness	2	2	0.6%	1	1	0.6%	0.0%	-1.5%	1.5%
Muscle Weakness	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
Osteoarthritis	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Spasms	20	19	5.9%	6	6	3.8%	2.1%	-2.1%	6.4%
Sprain	2	2	0.6%	1	1	0.6%	0.0%	-1.5%	1.5%
Other Musculoskeletal Pain, Specify Location	6	6	1.9%	5	5	3.1%	-1.3%	-4.1%	1.6%
Adjacent Segment Degeneration	7	7	2.2%	6	6	3.8%	-1.6%	-4.7%	1.5%
Cervical Pain	41	41	12.8%	18	17	10.7%	2.1%	-4.1%	8.3%
Lumbar Pain	1	1	0.3%	1	1	0.6%	-0.3%	-1.5%	0.9%
Facet Joint Deterioration	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Soft Tissue Injury/Inflammation	0	0	0.0%	2	2	1.3%	-1.3%	-2.5%	0.0%
Other Musculoskeletal and Connective Tissue Disorder	3	3	0.9%	2	2	1.3%	-0.3%	-2.3%	1.6%
<b>Nervous System Disorders</b>	<b>78</b>	<b>65</b>	<b>20.2%</b>	<b>44</b>	<b>39</b>	<b>24.5%</b>	<b>-4.3%</b>	<b>-12.1%</b>	<b>3.6%</b>
Dizziness	2	2	0.6%	0	0	0.0%	0.6%	-0.6%	1.8%
Dysesthesia	2	2	0.6%	1	1	0.6%	0.0%	-1.5%	1.5%
Dysphasia	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
Headache	5	5	1.6%	3	3	1.9%	-0.3%	-2.8%	2.1%
Numbness/Tingling	15	14	4.4%	4	4	2.5%	1.8%	-1.8%	5.5%
Paresthesia	0	0	0.0%	2	2	1.3%	-1.3%	-2.5%	0.0%
Radiculopathy	51	48	15.0%	33	30	18.9%	-3.9%	-10.9%	3.1%
Weakness	2	2	0.6%	0	0	0.0%	0.6%	-0.6%	1.8%
Other Nervous System Disorder	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
<b>Psychiatric Disorders</b>	<b>2</b>	<b>2</b>	<b>0.6%</b>	<b>1</b>	<b>1</b>	<b>0.6%</b>	<b>0.0%</b>	<b>-1.5%</b>	<b>1.5%</b>
Anxiety Disorders	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Insomnia	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Opioid Dependency	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%

	prodisc® C (N= 321)			Mobi C (N= 159)			Group Difference <sup>†</sup>		
	Events	Subjs	%*	Events	Subjs	%*	Δ	LB	UB
<b>Renal and Urinary Disorders</b>	<b>2</b>	<b>2</b>	<b>0.6%</b>	<b>0</b>	<b>0</b>	<b>0.0%</b>	<b>0.6%</b>	<b>-0.6%</b>	<b>1.8%</b>
Urinary Tract Infection	2	2	0.6%	0	0	0.0%	0.6%	-0.6%	1.8%
<b>Respiratory, Thoracic and Mediastinal Disorders</b>	<b>11</b>	<b>11</b>	<b>3.4%</b>	<b>2</b>	<b>2</b>	<b>1.3%</b>	<b>2.2%</b>	<b>-0.9%</b>	<b>5.3%</b>
Dyspnea	3	3	0.9%	0	0	0.0%	0.9%	-0.6%	2.4%
Hoarseness	4	4	1.2%	1	1	0.6%	0.6%	-1.3%	2.5%
Pneumonia	2	2	0.6%	0	0	0.0%	0.6%	-0.6%	1.8%
Pulmonary Embolism	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Airway Obstruction	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Other Respiratory, Thoracic and Medistinal Disorders Disorder	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
<b>Skin and Subcutaneous Tissue Disorders</b>	<b>8</b>	<b>8</b>	<b>2.5%</b>	<b>5</b>	<b>4</b>	<b>2.5%</b>	<b>0.0%</b>	<b>-3.0%</b>	<b>2.9%</b>
Hematoma	5	5	1.6%	1	1	0.6%	0.9%	-1.2%	3.0%
Seroma	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
Wound complications (eg., dehiscence, bruising) and soft tissue damage	2	2	0.6%	2	2	1.3%	-0.6%	-2.4%	1.1%
Wound secretions / drainage	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Other Skin and Subcutaneous Tissue Disorder	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
<b>Vascular Disorders</b>	<b>1</b>	<b>1</b>	<b>0.3%</b>	<b>0</b>	<b>0</b>	<b>0.0%</b>	<b>0.3%</b>	<b>-0.6%</b>	<b>1.2%</b>
Neurovascular Injury	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
<b>Device (non system specific)</b>	<b>11</b>	<b>10</b>	<b>3.1%</b>	<b>4</b>	<b>4</b>	<b>2.5%</b>	<b>0.6%</b>	<b>-2.6%</b>	<b>3.8%</b>
Implant Loosening	2	2	0.6%	0	0	0.0%	0.6%	-0.6%	1.8%
Implant Malalignment	1	1	0.3%	1	1	0.6%	-0.3%	-1.5%	0.9%
Implant Migration	6	6	1.9%	2	2	1.3%	0.6%	-1.8%	3.0%
Implant/Joint Noise	2	2	0.6%	1	1	0.6%	0.0%	-1.5%	1.5%
<b>Other Complications/Events</b>	<b>3</b>	<b>3</b>	<b>0.9%</b>	<b>2</b>	<b>2</b>	<b>1.3%</b>	<b>-0.3%</b>	<b>-2.3%</b>	<b>1.6%</b>
Trauma	2	2	0.6%	2	2	1.3%	-0.6%	-2.4%	1.1%
Adverse Reaction to Medication	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%

*Serious Adverse Events*

**Table 16** below presents a summary of all SAEs for all investigational prodisc® C SK and prodisc® C Vivo subjects and Mobi-C control subjects in the ITT analysis population (N=480). No SAEs had a rate of 5% or more.

**Table 4: Serious Adverse Events by AE Code - (ITT Analysis Set N= 480)**

	prodisc® C (N= 321)			Mobi C (N= 159)			Group Difference <sup>†</sup>		
	Events	Subjs	%*	Events	Subjs	%*	Δ	LB	UB
<b>All</b>	<b>72</b>	<b>60</b>	<b>18.7%</b>	<b>31</b>	<b>28</b>	<b>17.6%</b>	<b>1.1%</b>	<b>-6.3%</b>	<b>8.4%</b>
<b>Cardiac Disorders</b>	<b>3</b>	<b>3</b>	<b>0.9%</b>	<b>1</b>	<b>1</b>	<b>0.6%</b>	<b>0.3%</b>	<b>-1.4%</b>	<b>2.0%</b>
Acute Coronary Syndrome	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Chest Pain	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
Myocardial Infarction	2	2	0.6%	0	0	0.0%	0.6%	-0.6%	1.8%
<b>Endocrine Disorders</b>	<b>2</b>	<b>1</b>	<b>0.3%</b>	<b>0</b>	<b>0</b>	<b>0.0%</b>	<b>0.3%</b>	<b>-0.6%</b>	<b>1.2%</b>
Diabetes Mellitus	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Other Endocrine Disorder	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
<b>Eye Disorders</b>	<b>0</b>	<b>0</b>	<b>0.0%</b>	<b>1</b>	<b>1</b>	<b>0.6%</b>	<b>-0.6%</b>	<b>-1.5%</b>	<b>0.2%</b>
Retinal Detachment	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
<b>Gastrointestinal Disorders</b>	<b>4</b>	<b>4</b>	<b>1.2%</b>	<b>2</b>	<b>2</b>	<b>1.3%</b>	<b>0.0%</b>	<b>-2.1%</b>	<b>2.1%</b>
Gastroesophageal Reflux Disease	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Gastrointestinal Pain, Specify Location	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Pancreatitis	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
Appendicitis	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
Other Gastrointestinal Disorder	2	2	0.6%	0	0	0.0%	0.6%	-0.6%	1.8%
<b>General Disorders and Administration</b>	<b>1</b>	<b>1</b>	<b>0.3%</b>	<b>0</b>	<b>0</b>	<b>0.0%</b>	<b>0.3%</b>	<b>-0.6%</b>	<b>1.2%</b>
General Disorders and Administrative Site Conditions - COVID-19	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
<b>Hepatobiliary Disorders</b>	<b>3</b>	<b>3</b>	<b>0.9%</b>	<b>0</b>	<b>0</b>	<b>0.0%</b>	<b>0.9%</b>	<b>-0.6%</b>	<b>2.4%</b>
Gallbladder Obstruction	2	2	0.6%	0	0	0.0%	0.6%	-0.6%	1.8%
Other Hepatobiliary Disorders	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
<b>Infections and Infestations</b>	<b>5</b>	<b>5</b>	<b>1.6%</b>	<b>3</b>	<b>3</b>	<b>1.9%</b>	<b>-0.3%</b>	<b>-2.8%</b>	<b>2.1%</b>
Infection, Surgical Site	3	3	0.9%	0	0	0.0%	0.9%	-0.6%	2.4%
Infection, Not at Surgical Site	1	1	0.3%	1	1	0.6%	-0.3%	-1.5%	0.9%
Sinusitis	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Sepsis	0	0	0.0%	2	2	1.3%	-1.3%	-2.5%	0.0%
<b>Musculoskeletal and Connective Tissue Disorders</b>	<b>17</b>	<b>15</b>	<b>4.7%</b>	<b>8</b>	<b>7</b>	<b>4.4%</b>	<b>0.3%</b>	<b>-3.7%</b>	<b>4.2%</b>
Fracture, Any Bone	2	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Joint Pain	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Osteoarthritis	1	1	0.3%	2	2	1.3%	-0.9%	-2.4%	0.6%
Adjacent Segment Degeneration	1	1	0.3%	1	1	0.6%	-0.3%	-1.5%	0.9%
Lumbar Degenerative Disc Disease	4	4	1.2%	1	1	0.6%	0.6%	-1.3%	2.5%
Pseudarthrosis	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
Cervical Pain	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
Lumbar Pain	3	3	0.9%	2	2	1.3%	-0.3%	-2.3%	1.6%
Spinal Stenosis	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Spondylosis	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Other Musculoskeletal and Connective Tissue Disorder	3	3	0.9%	0	0	0.0%	0.9%	-0.6%	2.4%
<b>Nervous System Disorders</b>	<b>8</b>	<b>8</b>	<b>2.5%</b>	<b>6</b>	<b>6</b>	<b>3.8%</b>	<b>-1.3%</b>	<b>-4.5%</b>	<b>1.9%</b>
Compressive Neuropathy	0	0	0.0%	2	2	1.3%	-1.3%	-2.5%	0.0%
Radiculopathy	7	7	2.2%	4	4	2.5%	-0.3%	-3.2%	2.5%
Other Nervous System Disorder	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
<b>Psychiatric Disorders</b>	<b>2</b>	<b>2</b>	<b>0.6%</b>	<b>0</b>	<b>0</b>	<b>0.0%</b>	<b>0.6%</b>	<b>-0.6%</b>	<b>1.8%</b>
Depression	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Other Psychiatric Disorder	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
<b>Renal and Urinary Disorders</b>	<b>1</b>	<b>1</b>	<b>0.3%</b>	<b>0</b>	<b>0</b>	<b>0.0%</b>	<b>0.3%</b>	<b>-0.6%</b>	<b>1.2%</b>
Urinary Tract Infection	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
<b>Respiratory, Thoracic and Mediastinal Disorders</b>	<b>4</b>	<b>4</b>	<b>1.2%</b>	<b>0</b>	<b>0</b>	<b>0.0%</b>	<b>1.2%</b>	<b>-0.5%</b>	<b>3.0%</b>
Pneumonia	2	2	0.6%	0	0	0.0%	0.6%	-0.6%	1.8%
Pulmonary Embolism	2	2	0.6%	0	0	0.0%	0.6%	-0.6%	1.8%

	prodisc® C (N= 321)			Mobi C (N= 159)			Group Difference <sup>†</sup>		
	Events	Subjs	%*	Events	Subjs	%*	Δ	LB	UB
<b>Skin and Subcutaneous Tissue Disorders</b>	<b>3</b>	<b>3</b>	<b>0.9%</b>	<b>1</b>	<b>1</b>	<b>0.6%</b>	<b>0.3%</b>	<b>-1.4%</b>	<b>2.0%</b>
Hematoma	2	2	0.6%	0	0	0.0%	0.6%	-0.6%	1.8%
Seroma	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
Wound complications (eg., dehiscence, bruising) and soft tissue damage	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
<b>Vascular Disorders</b>	<b>3</b>	<b>3</b>	<b>0.9%</b>	<b>1</b>	<b>1</b>	<b>0.6%</b>	<b>0.3%</b>	<b>-1.4%</b>	<b>2.0%</b>
Hypertension	1	1	0.3%	1	1	0.6%	-0.3%	-1.5%	0.9%
Neurovascular Injury	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
Thromboembolic Event	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%
<b>Device (non system specific)</b>	<b>6</b>	<b>5</b>	<b>1.6%</b>	<b>3</b>	<b>3</b>	<b>1.9%</b>	<b>-0.3%</b>	<b>-2.8%</b>	<b>2.1%</b>
Implant Loosening	2	2	0.6%	0	0	0.0%	0.6%	-0.6%	1.8%
Implant Malalignment	0	0	0.0%	1	1	0.6%	-0.6%	-1.5%	0.2%
Implant Migration	4	4	1.2%	2	2	1.3%	0.0%	-2.1%	2.1%
<b>Other Complications/Events</b>	<b>10</b>	<b>10</b>	<b>3.1%</b>	<b>5</b>	<b>5</b>	<b>3.1%</b>	<b>0.0%</b>	<b>-3.3%</b>	<b>3.3%</b>
Surgery at a location other than the spine	3	3	0.9%	1	1	0.6%	0.3%	-1.4%	2.0%
Trauma	1	1	0.3%	3	3	1.9%	-1.6%	-3.3%	0.2%
Cancer	5	5	1.6%	1	1	0.6%	0.9%	-1.2%	3.0%
Other Event, Describe	1	1	0.3%	0	0	0.0%	0.3%	-0.6%	1.2%

*Serious Adverse Events Time course*

**Table 17** presents the SAEs through Month 24 for both treatment groups. The majority of SAEs occurred between Month 6 and Month 12 for the investigational group, and between Month 3 and Month 6 for the control group. While not shown, the majority of device- or procedure-related SAEs occurred between 0 and 30 days post-operatively for the investigational group, and between 30 and 90 days post-operatively for the control group.

**Table 5: Serious Adverse Events (Time course) (ITT Analysis Set N= 480)**

	Days Post-Op																			
	Missing		<0		0-2		2-30		30-90		90-180		180-365		365-730		730-790		Total	
	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C
<b>All</b>	2	1	0	0	3	0	7	3	8	3	11	8	15	6	15	7	11	3	72	31
<b>Cardiac Disorders</b>	0	0	0	0	0	0	0	0	0	0	0	0	2	1	1	0	0	0	3	1
Acute Coronary Syndrome	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1	0
Chest Pain	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1
Myocardial Infarction	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0	0	0	2	0
<b>Endocrine Disorders</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0	2	0
Diabetes Mellitus	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0
Other Endocrine Disorder	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0
<b>Eye Disorders</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1
Retinal Detachment	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	1
<b>Gastrointestinal Disorders</b>	0	0	0	0	0	0	1	2	0	0	1	0	1	0	0	0	1	0	4	2
Gastroesophageal Reflux Disease	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	0
Gastrointestinal Pain, Specify Location	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1	0
Pancreatitis	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1
Appendicitis	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1
Other Gastrointestinal Disorder	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1	0	2	0
<b>General Disorders and Administration</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0
General Disorders and Administrative Site Conditions - COVID-19	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0
<b>Hepatobiliary Disorders</b>	0	0	0	0	0	0	1	0	1	0	0	0	1	0	0	0	0	0	3	0
Gallbladder Obstruction	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	0	0	0	2	0
Other Hepatobiliary Disorders	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1	0
<b>Infections and Infestations</b>	0	0	0	0	0	0	1	1	1	0	1	0	0	0	1	1	1	1	5	3
Infection, Surgical Site	0	0	0	0	0	0	1	0	0	0	1	0	0	0	1	0	0	0	3	0
Infection, Not at Surgical Site	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	0	1	1
Sinusitis	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0
Sepsis	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0	2

	Days Post-Op																				
	Missing		<0		0-2		2-30		30-90		90-180		180-365		365-730		730-790		Total		
	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C	
<b>Musculoskeletal and Connective Tissue Disorders</b>	<b>1</b>	<b>1</b>	<b>0</b>	<b>2</b>	<b>0</b>	<b>5</b>	<b>1</b>	<b>4</b>	<b>3</b>	<b>2</b>	<b>3</b>	<b>3</b>	<b>0</b>	<b>17</b>	<b>8</b>						
Fracture, Any Bone	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	2	0
Joint Pain	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	0
Osteoarthritis	0	1	0	0	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	1	2
Adjacent Segment Degeneration	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	1	0	0	1	1
Lumbar Degenerative Disc Disease	0	0	0	0	0	0	0	0	0	1	0	1	0	1	1	1	0	0	0	4	1
Pseudarthrosis	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	1
Cervical Pain	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1
Lumbar Pain	0	0	0	0	0	0	0	0	0	0	0	2	0	1	1	0	1	0	0	3	2
Spinal Stenosis	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	0
Spondylosis	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0
Other Musculoskeletal and Connective Tissue Disorder	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	2	0	3	0
<b>Nervous System Disorders</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>1</b>	<b>1</b>	<b>3</b>	<b>3</b>	<b>0</b>	<b>1</b>	<b>2</b>	<b>1</b>	<b>1</b>	<b>0</b>	<b>8</b>	<b>6</b>	
Compressive Neuropathy	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	2
Radiculopathy	0	0	0	0	0	0	1	0	1	1	3	1	0	1	1	1	1	0	0	7	4
Other Nervous System Disorder	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0	0
<b>Psychiatric Disorders</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>2</b>	<b>0</b>
Depression	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1	0
Other Psychiatric Disorder	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0
<b>Renal and Urinary Disorders</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>1</b>	<b>0</b>									
Urinary Tract Infection	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	1	0
<b>Respiratory, Thoracic and Mediastinal Disorders</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>4</b>	<b>0</b>
Pneumonia	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	1	0	0	0	2	0
Pulmonary Embolism	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	0	0	0	0	2	0
<b>Skin and Subcutaneous Tissue Disorders</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>2</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>3</b>	<b>1</b>								
Hematoma	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0
Seroma	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	1
Wound complications (eg., dehiscence, bruising) and soft tissue damage	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	1	0

	Days Post-Op																			
	Missing		<0		0-2		2-30		30-90		90-180		180-365		365-730		730-790		Total	
	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C
<b>Vascular Disorders</b>	0	0	0	0	0	0	1	0	1	0	0	0	0	0	1	0	0	1	3	1
Hypertension	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	1	1
Neurovascular Injury	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1	0
Thromboembolic Event	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0
<b>Device (non system specific)</b>	0	0	0	0	0	0	0	0	0	1	1	2	3	0	1	0	1	0	6	3
Implant Loosening	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0	2	0
Implant Malalignment	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1
Implant Migration	0	0	0	0	0	0	0	0	0	1	1	1	2	0	1	0	0	0	4	2
<b>Other Complications/Events</b>	1	0	0	0	0	0	0	0	0	0	0	2	3	1	3	1	3	1	10	5
Surgery at a location other than the spine	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	1	2	0	3	1
Trauma	0	0	0	0	0	0	0	0	0	0	0	2	1	1	0	0	0	0	1	3
Cancer	1	0	0	0	0	0	0	0	0	0	0	0	1	0	3	0	0	1	5	1
Other Event, Describe	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0

Secondary Surgical Interventions

A total of 9 subjects (3.1% - 9/321) experienced an SSI through Month 24 in the investigational group, while a total of 6 subjects (4.3% - 6/159) experienced an SSI through Month 24 in the control group. In both cases, removals were the most frequent type of SSI. **Table 18** shows the SSI time course through Month 24 for both groups.

**Table 18: SSI Time course by Treatment Type – AT Analysis Set N-431**

Treatment Group	SSI Type	Event Time-Course (months)					Total Subjects
		<1.5	1.5-3	3-6	6-12	12-24	
Prodisc C	Removal	1	-	1	1	5*	7
	Revision	-	-	-	-	-	-
	Reoperation	-	-	-	1	1	2
	Supplemental Fixation	-	-	-	-	-	-
<b>Total Events (Subjects)</b>		<b>1</b>	<b>-</b>	<b>1</b>	<b>2</b>	<b>6</b>	<b>9 subjects</b>
Mobi-C (Control)	Removal	-	1	1	1	2	5
	Revision	-	-	-	-	-	-
	Reoperation	-	-	1	-	-	1
	Supplemental Fixation	-	-	-	-	-	-
<b>Total Events (Subjects)</b>			<b>1</b>	<b>2</b>	<b>1</b>	<b>2</b>	<b>6 subjects</b>

\*One subject had two SSIs

2. Effectiveness Results

This clinical trial was designed to test the non-inferiority of the investigational device (prodisc® C SK and prodisc® C Vivo) as compared to the control device (Mobi-C) when used at two levels in the spine through the use of a primary composite endpoint.

Overall Success

A subject was considered a study success if the following criteria were met:

- 15-point improvement in NDI Score (out of 100) in subjects at the Month 24 timepoint compared with baseline;
- Maintenance or improvement in neurological status (motor and sensory only) at Month 24 compared to baseline;
- No secondary surgical interventions (revision, removal, re-operation, supplemental fixation) at the index level(s); and,
- Absence of major device-related AEs defined as radiographic failure, neurological failure, or failure by AE as adjudicated by the CEC.

Overall success was determined based on the mITT Analysis Set at Month 24. No data was imputed. The primary overall success outcomes are presented in **Table 19**.

**Table 19: Overall Success (mITT Analysis Set, N=433)**

Row		prodisc® C			mobi-c			Group Difference			PostProb NI [3]
		N	n	%	N	n	%	$\Delta$ [2]	LB [1]	UB [1]	
1	Implanted	293	291	99.3%	140	140	100.0%	-0.7%	-2.5%	2.2%	
2	No secondary surgical intervention	293	284	96.9%	140	134	95.7%	1.2%	-2.4%	6.3%	
3	NDI 15-point Responder†	244	229	93.9%	121	109	90.1%	3.8%	-2.0%	11.0%	
4	No Neurological Deterioration (CEC)†	246	241	98.0%	125	121	96.8%	1.2%	-2.2%	6.2%	
5	No Major Adverse Event (CEC)	293	292	99.7%	140	140	100.0%	-0.3%	-2.0%	2.5%	
6	CCS Completers vs. Current mobi-C	253	221	87.1%	127	107	83.7%	3.3%	-3.6%	10.8%	>0.999

[1] 95% Exact binomial CI.  
[2] The top frame is the difference in observed proportions; the bottom frame is the difference between beta-distributions.  
[3] Posterior probability of Non-inferiority (NI) (delta = -10%).  
† Subjects censored at Index level secondary surgical interventions.  
All Bayesian distributions based on uniform (1, 1) prior. 5000 imputations and 10000 beta draws used.  
Source: CS2 Results PMA Lock 3.SAS; CS2 Primary v1 2025-04-14 mITT.R; Analyzed: 14APR2025

The success rate for the investigational group was 87.1% (221/253) as compared to a success rate of 83.7% (107/127) for the control group. Posterior probability is shown in row 6 to demonstrate that non-inferiority has been achieved. In this study, the posterior probability of greater than 99.99% indicates there is greater than 99.99% chance that the investigational group performs at least as well as the control group (i.e., is non-inferior). The study's pre-specified success criterion required this probability to exceed 96.7% to declare success, which was achieved in this analysis.

A secondary supporting sensitivity analysis of the primary endpoint was performed for the PP Analysis Set (which per the applicant's original protocol, was the primary analysis population). The results were similar, with a success rate of 88.7% (219/246) as compared to a success rate of 84.0% (104/123) for the control group. Non-inferiority was also demonstrated in the PP Analysis Set.

### Tipping Point Analysis

A total of 40 investigational subjects did not have a Month 24 CCS; 14 had not yet reached Month 24, 5 were not yet overdue, and 21 were missing for other reasons. Likewise, there were a total of 13 control that did not have a Month 24 CCS; 2 had not yet reached Month 24, 2 were not yet overdue, and 9 were missing for other reasons.

A tipping point analysis was conducted to investigate the chance of the study conclusions changing as a result of this missing data. An assumption was made that the data is missing-at-random, thereby making no assumptions about their missingness. The results of the tipping point analysis indicated that the results were tipped only 19.5% of the time. In other words, non-inferiority was met 80.5% of the time with these imputations of the missing data, indicating robustness in the non-inferiority claim.

### Composite Clinical Success Subcomponents

In looking at the individual subcomponents of the CCS in **Table 19**, the results are similar between both treatment groups. Row 2 identifies that 96.9% (284/293) of the investigational subjects and 95.7% (134/140) of the control subjects did not experience an SSI. Row 3 indicates that 93.9% (229/244) of the investigational subjects and 90.1% (109/121) of the control subjects demonstrated meaningful improvement in their NDI assessment at Month 24 compared to baseline. As for Row 4, the reported results indicate that 98.0% (241/246) of the investigational subjects and 96.8% (121/125) of the control subjects did not experience neurological

deterioration. Lastly, Row 5 identifies that 99.7% (292/293) of the investigational subjects and 100% (140/140) of the control subjects did not experience a major device-related AE.

### Secondary Endpoint Analyses

In addition to the CCS subcomponents, a number of secondary endpoints were evaluated in the mITT Analysis Set, including: neck pain, arm pain, and subject quality of life.

#### **Neck Pain – VAS**

A 100mm VAS was administered to subjects in order to assess neck pain. In the investigational group, the pre-operative neck pain VAS mean score was 73.8mm, and significantly dropped post-operatively to a Month 24 neck pain VAS mean score of 16.6mm. Similarly, in the control group, the pre-operative neck pain VAS mean score was 74.3mm, and also significantly dropped post-operatively to a Month 24 neck pain VAS mean score of 16.6mm. An additional analysis looked at how many subjects responded to treatment with at least a 20mm reduction in VAS. **Table 20** illustrates that a large proportion of subjects in both groups experienced at least a 20mm reduction in their neck pain VAS score across all post-operative timepoints. At Month 24, 88.1% (214/243) of subjects in the investigational group reported at least a 20mm reduction in their neck pain VAS score, and 86.9% (106/122) of subjects in the control group reported at least a 20mm reduction in their neck pain VAS score.

**Table 20: VAS (Neck) 20mm Responder (mITT Analysis Set N=433, Excluding subjects with SSIs at Index Level)**

	prodisc® C			Mobi C			Group Difference*		
	N	n	%	N	n	%	Δ	LB	UB
Week 06	275	244	88.7%	135	120	88.9%	-0.2%	-6.6%	6.3%
Month 03	280	258	92.1%	136	127	93.4%	-1.2%	-6.5%	4.0%
Month 06	282	260	92.2%	136	120	88.2%	4.0%	-2.3%	10.2%
Month 12	278	250	89.9%	130	112	86.2%	3.8%	-3.1%	10.7%
Month 24	243	214	88.1%	122	106	86.9%	1.2%	-6.1%	8.4%

Subjects censored at Index level secondary surgical interventions.  
 \*Device group differences, Nominal 95% CI, and two-sided asymptomatic p-value.  
 Source: Table Clinical Follow-up mITT.sas; Analyzed: 13MAR2025

#### **Left Arm Pain – VAS**

A 100mm VAS was administered to subjects in order to assess left arm pain. In the investigational group, the pre-operative left arm pain VAS mean score was 53.2mm, and significantly dropped post-operatively to a Month 24 left arm pain VAS mean score of 11.9mm. Similarly, in the control group, the pre-operative left arm pain VAS mean score was 52.5mm, and also significantly dropped post-operatively to a Month 24 left pain VAS mean score of 13.9mm. An additional analysis looked at how many subjects responded to treatment with at least a 20mm reduction in VAS. While not as high as the reduction in neck pain VAS, **Table 21** illustrates that a large proportion of subjects in both groups experienced at least a 20mm reduction in their left arm pain VAS score across all post-operative timepoints. At Month 24, 66.3% (161/243) of subjects in the investigational group reported at least a 20mm reduction in their left arm pain VAS score, and

62.3% (76/122) of subjects in the control group reported at least a 20mm reduction in their left arm pain VAS score.

**Table 21: VAS (left arm/shoulder) 20mm Responder (mITT Analysis Set N=433, Excluding subjects with SSIs at Index Level)**

	prodisc® C			Mobi C			Group Difference*		
	N	n	%	N	n	%	Δ	LB	UB
Week 06	276	189	68.5%	135	85	63.0%	5.5%	-4.3%	15.3%
Month 03	280	194	69.3%	136	89	65.4%	3.8%	-5.8%	13.5%
Month 06	282	201	71.3%	136	91	66.9%	4.4%	-5.1%	13.9%
Month 12	278	192	69.1%	130	81	62.3%	6.8%	-3.2%	16.7%
Month 24	243	161	66.3%	122	76	62.3%	4.0%	-6.5%	14.4%

Subjects censored at Index level secondary surgical interventions.  
 \*Device group differences, Nominal 95% CI, and two-sided asymptomatic p-value.  
 Source: Table Clinical Follow-up mITT.sas; Analyzed: 13MAR2025

**Right Arm Pain – VAS**

A 100mm VAS was administered to subjects in order to also assess right arm pain. In the investigational group, the pre-operative right arm pain VAS mean score was 52.0mm, and significantly dropped post-operatively to a Month 24 right arm pain VAS mean score of 14.1mm. Similarly, in the control group, the pre-operative right arm pain VAS mean score was 54.1mm, and also significantly dropped post-operatively to a Month 24 right arm pain VAS mean score of 11.4mm. An additional analysis was also carried out that looked at how many subjects responded to treatment with at least a 20mm reduction in VAS. While not as high as the reduction in neck pain VAS, but similar to the change in left arm pain VAS, **Table 22** illustrates that a large proportion of subjects in both groups experienced at least a 20mm reduction in their right arm pain VAS score across all post-operative timepoints. At Month 24, 65.8% (160/243) of subjects in the investigational group reported at least a 20mm reduction in their right arm pain VAS score, and 68.0% (83/122) of subjects in the control group reported at least a 20mm reduction in their right arm pain VAS score.

Interestingly, the applicant looked at the “worst” arm pain VAS for each subject. At Month 24, 84.8% (206/243) of subjects in the investigational group reported at least a 20mm reduction in their “worst” arm pain VAS score, and 85.2% (104/122) of subjects in the control group reported at least a 20mm reduction in their “worst” arm pain VAS score.

**Table 22: VAS (right arm/shoulder) 20mm Responder (mITT Analysis Set N=433, Excluding subjects with SSIs at Index Level)**

	prodisc® C			Mobi C			Group Difference*		
	N	n	%	N	n	%	Δ	LB	UB
Week 06	276	173	62.7%	135	95	70.4%	-7.7%	-17.3%	1.9%
Month 03	280	178	63.6%	136	90	66.2%	-2.6%	-12.4%	7.1%
Month 06	282	192	68.1%	136	93	68.4%	-0.3%	-9.8%	9.2%
Month 12	278	188	67.6%	130	85	65.4%	2.2%	-7.6%	12.1%
Month 24	243	160	65.8%	122	83	68.0%	-2.2%	-12.4%	8.0%

Subjects censored at Index level secondary surgical interventions.  
 \*Device group differences, Nominal 95% CI, and two-sided asymptomatic p-value.  
 Source: Table Clinical Follow-up mITT.sas; Analyzed: 13MAR2025

**Hoarseness – VAS**

A 100mm VAS was administered to subjects in order to also assess hoarseness. As shown in **Table 23**, in the investigational group, the pre-operative hoarseness VAS mean score was 19.0mm, and dropped post-operatively to a Month 24 right arm pain VAS mean score of 6.6mm. Similarly, in the control group, the pre-operative hoarseness VAS mean score was 27.2mm, and also dropped post-operatively to a Month 24 hoarseness VAS mean score of 5.7mm.

**Table 23: VAS Hoarseness Values Over Time (mITT Analysis Set N=433, Excluding subjects with SSIs at Index Level)**

	prodisc® C						Mobi C						Group Difference*		
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	Δ	LB	UB
PreOp	293	19.0	25.9	5.0	0.0	100.0	140	19.5	27.2	4.0	0.0	100.0	-0.6	-5.6	4.7
Week 06	275	10.2	18.1	2.0	0.0	100.0	135	9.6	18.3	2.0	0.0	100.0	0.6	-3.2	4.4
Month 03	280	6.1	12.8	1.0	0.0	85.0	136	6.1	13.6	1.0	0.0	68.0	0.0	-2.4	2.9
Month 06	282	5.4	13.3	0.0	0.0	97.0	136	5.7	13.0	1.0	0.0	72.0	-0.3	-3.0	2.4
Month 12	278	5.9	13.6	1.0	0.0	84.0	130	6.3	15.7	1.0	0.0	100.0	-0.4	-3.3	2.7
Month 24	243	6.6	15.2	1.0	0.0	98.0	122	5.7	13.3	0.0	0.0	79.0	0.8	-2.4	4.0

Subjects censored at Index level secondary surgical interventions.  
 \*Device group mean differences and 95% Credible Intervals.  
 Source: Table Clinical Follow-up mITT.sas; Analyzed: 13MAR2025

**Dysphagia Handicap Index**

DHI was administered to subjects in order to assess swallowing difficulties. As **Table 24** reports, in the investigational group, the pre-operative DHI mean score was 10.9, and dropped post-operatively to a Month 24 DHI mean score of 6.8. Similarly, in the control group, the pre-operative DHI mean score was 11.1, and also dropped post-operatively to a Month 24 DHI mean score of 7.7. This suggest that as a whole, both the investigational and control treatments do not significantly contribute to development of swallowing difficulties.

**Table 24: DHI Scores Over Time (mITT Analysis Set N=433, Excluding subjects with SSIs at Index Level)**

	prodisc® C						Mobi C						Group Difference*		
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	Δ	LB	UB
PreOp	291	10.9	15.4	4.0	0.0	98.0	140	11.1	14.9	6.0	0.0	64.0	-0.2	-3.2	2.8
Week 06	271	10.2	12.5	4.0	0.0	74.0	133	10.9	12.9	6.0	0.0	68.0	-0.6	-3.2	2.1
Month 03	279	6.9	10.2	2.0	0.0	66.0	136	8.4	11.6	3.0	0.0	52.0	-1.5	-3.6	0.7
Month 06	277	6.2	11.0	2.0	0.0	92.0	136	8.0	12.2	3.0	0.0	58.0	-1.9	-4.2	0.4
Month 12	276	6.4	11.5	2.0	0.0	84.0	130	7.3	12.0	2.0	0.0	52.0	-0.9	-3.3	1.5
Month 24	244	6.8	11.3	2.0	0.0	60.0	121	7.7	11.6	2.0	0.0	56.0	-0.9	-3.3	1.7

Subjects censored at Index level secondary surgical interventions.  
 \*Device group mean differences and 95% Credible Intervals.  
 Source: Table Clinical Follow-up mITT.sas; Analyzed: 13MAR2025

**SF-12 Physical Component Scores**

The results of the PCS portion of the SF-12 are shown in **Table 25**. In the investigational group, the pre-operative SF-12 PCS mean score was 31.1, and increased post-operatively to a Month 24 SF-12 PCS mean score of 48.7. Similarly, in the control group, the pre-operative SF-12 PCS mean score was 32.0, and also increased post-operatively to a Month 24 SF-12 PCS mean score of 48.0.

**Table 25: SF-12 (PCS) values over time (mITT Analysis Set N=433, Excluding subjects with SSIs at Index Level)**

	prodisc® C						Mobi C						Group Difference*		
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	Δ	LB	UB
PreOp	293	31.1	8.1	30.6	11.4	54.5	140	32.0	8.6	32.3	9.2	53.9	-0.9	-2.5	0.8
Week 06	272	44.5	10.0	46.0	14.7	62.7	134	44.2	10.1	46.0	15.9	60.5	0.3	-1.7	2.5
Month 03	278	47.1	9.7	48.5	15.3	62.4	136	47.9	8.9	50.6	20.9	62.1	-0.8	-2.7	1.1
Month 06	279	48.0	9.9	50.2	11.2	66.8	136	47.8	10.4	50.7	17.4	62.1	0.2	-1.9	2.1
Month 12	277	48.5	10.8	52.4	13.2	68.9	130	47.3	10.7	51.3	15.0	62.1	1.3	-0.9	3.6
Month 24	243	48.7	10.9	53.2	7.8	65.5	121	48.0	10.1	50.6	17.3	62.1	0.7	-1.7	2.9

Subjects censored at Index level secondary surgical interventions.  
 \*Device group mean differences and 95% Credible Intervals.  
 Source: Table Clinical Follow-up mITT.sas; Analyzed: 13MAR2025

**SF-12 Mental Component Scores**

The results of the MCS portion of the SF-12 are shown in **Table 26**. In the investigational group, the pre-operative SF-12 MCS mean score was 44.0, and increased post-operatively to a Month 24 SF-12 MCS mean score of 52.0. Similarly, in the control group, the pre-operative SF-12 MCS mean score was 42.7, and also increased post-operatively to a Month 24 SF-12 MCS mean score of 51.2.

**Table 26: SF-12 (MCS) Values Over Time (mITT Analysis Set N=433, Excluding subjects with SSIs at Index Level)**

	prodisc® C						Mobi C						Group Difference*		
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	Δ	LB	UB
PreOp	293	44.0	12.1	43.1	15.6	69.6	140	42.7	13.4	43.0	9.4	69.2	1.4	-1.0	3.9
Week 06	272	53.3	8.7	55.6	23.9	72.8	134	51.6	10.3	55.0	12.9	67.3	1.7	-0.1	3.7
Month 03	278	53.4	9.0	55.8	19.9	69.3	136	51.8	10.4	55.7	17.2	66.3	1.6	-0.3	3.5
Month 06	279	53.2	9.5	56.8	19.8	72.7	136	51.6	10.4	55.2	25.8	68.6	1.6	-0.4	3.5
Month 12	277	52.9	10.0	57.1	15.9	66.8	130	52.2	9.8	55.2	15.9	67.5	0.8	-1.2	3.0
Month 24	243	52.0	10.3	55.8	11.5	68.6	121	51.2	10.2	54.8	21.3	64.7	0.8	-1.5	2.9

Subjects censored at Index level secondary surgical interventions.  
 \*Device group mean differences and 95% Credible Intervals.  
 Source: Table Clinical Follow-up mITT.sas; Analyzed: 13MAR2025

**Odom’s Criteria**

Odom’s Criteria consist of a 4-point rating scale for surgeons to assess clinical outcomes following cervical spine surgery. **Table 27** provides the ratings for Odom’s Criteria in the clinical study. In both groups, the predominant response is “Excellent” or “Good” at each post-operative timepoint. At Month 24, a response of “Excellent” was reported in 89.5% (221/247) of investigational cases, and similarly, a response of “Excellent” was reported in 86.5% (109/126) of control cases.

**Table 27: Odom’s Criteria (mITT Analysis Set N=433, Excluding subjects with SSIs at Index Level)**

	Week 06						Month 3						Month 6					
	prodisc® C			Mobi C			prodisc® C			Mobi C			prodisc® C			Mobi C		
	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%
Excellent	283	240	84.8%	138	111	80.4%	286	258	90.2%	137	119	86.9%	285	261	91.6%	137	115	83.9%
Good	283	36	12.7%	138	22	15.9%	286	25	8.7%	137	14	10.2%	285	20	7.0%	137	17	12.4%
Fair	283	7	2.5%	138	4	2.9%	286	2	0.7%	137	4	2.9%	285	3	1.1%	137	5	3.6%
Poor	283	0	0.0%	138	1	0.7%	286	1	0.3%	137	0	0.0%	285	1	0.4%	137	0	0.0%

Subjects censored at Index level secondary surgical interventions.  
 Source: Table Clinical Follow-up mITT.sas; Analyzed: 13MAR2025

	Month 12						Month 24					
	prodisc® C			Mobi C			prodisc® C			Mobi C		
	N	n	%	N	n	%	N	n	%	N	n	%
Excellent	282	257	91.1%	131	115	87.8%	247	221	89.5%	126	109	86.5%
Good	282	20	7.1%	131	9	6.9%	247	17	6.9%	126	10	7.9%
Fair	282	4	1.4%	131	6	4.6%	247	7	2.8%	126	6	4.8%
Poor	282	1	0.4%	131	1	0.8%	247	2	0.8%	126	1	0.8%

Subjects censored at Index level secondary surgical interventions.  
Source: Table Clinical Follow-up mITT.sas; Analyzed: 13MAR2025

### Nurick Scale

The Nurick Scale is a 6-grade classification system that is used for surgeons to assess the level of cervical spondylotic myelopathy while conducting a physical examination. The scale includes: Grade 0 (normal gait); Grade 1 (signs of spinal cord compression but with normal gait); Grade 2 (slight difficulty in walking that does not prevent full-time employment); Grade 3 (Difficulty in walking that prevents full-time employment or daily tasks, but does not require assistance with walking); Grade 4 (able to walk only with someone else’s help or with the aid of a frame); and Grade 5 (chair-bound or bedridden). **Table 28** provides the gradings on the Nurick Scale pre-operatively and through the post-operative timepoints. The vast majority of subjects were Grade 0 pre-operatively and post-operatively, although there was a general increase in the proportion of subjects determined to be Grade 0 or Grade 1; by Month 24, only n=1 subject in the investigational group was classified as Grade 2, with all other subjects in both groups being classified as Grade 0 or 1.

**Table 28: Myelopathy – Nurick Scale (mITT Analysis Set N=433, Excluding subjects with SSIs at Index Level)**

	PreOp						Week 06						Month 3					
	prodisc® C			Mobi C			prodisc® C			Mobi C			prodisc® C			Mobi C		
	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%
0	291	224	77.0%	139	107	77.0%	283	279	98.6%	138	131	94.9%	286	283	99.0%	137	133	97.1%
1	291	50	17.2%	139	25	18.0%	283	2	0.7%	138	6	4.3%	286	2	0.7%	137	4	2.9%
2	291	7	2.4%	139	6	4.3%	283	0	0.0%	138	1	0.7%	286	1	0.3%	137	0	0.0%
3	291	8	2.7%	139	1	0.7%	283	1	0.4%	138	0	0.0%	286	0	0.0%	137	0	0.0%
4	291	1	0.3%	139	0	0.0%	283	1	0.4%	138	0	0.0%	286	0	0.0%	137	0	0.0%
5	291	1	0.3%	139	0	0.0%	283	0	0.0%	138	0	0.0%	286	0	0.0%	137	0	0.0%

Source: Table Clinical Follow-up mITT.sas; Analyzed: 13MAR2025

	Month 6						Month 12						Month 24					
	prodisc® C			Mobi C			prodisc® C			Mobi C			prodisc® C			Mobi C		
	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%
0	285	281	98.6%	137	129	94.2%	282	278	98.6%	131	128	97.7%	247	241	97.6%	126	124	98.4%
1	285	3	1.1%	137	8	5.8%	282	3	1.1%	131	3	2.3%	247	5	2.0%	126	2	1.6%
2	285	0	0.0%	137	0	0.0%	282	0	0.0%	131	0	0.0%	247	1	0.4%	126	0	0.0%
3	285	1	0.4%	137	0	0.0%	282	1	0.4%	131	0	0.0%	247	0	0.0%	126	0	0.0%
4	285	0	0.0%	137	0	0.0%	282	0	0.0%	131	0	0.0%	247	0	0.0%	126	0	0.0%
5	285	0	0.0%	137	0	0.0%	282	0	0.0%	131	0	0.0%	247	0	0.0%	126	0	0.0%

Subjects censored at Index level secondary surgical interventions.  
Source: Table Clinical Follow-up mITT.sas; Analyzed: 13MAR2025

### Treatment Satisfaction

A Treatment Satisfaction questionnaire was administered to all subjects irrespective of intra-operative deviation or SSI.

In response to the question, “How satisfied are you with the results of your neck operation,” approximately four-fifths of subjects in both groups indicated that they were “Extremely Satisfied” at all post-operative timepoints, with 81.1% (202/249) of investigational subjects and 78.9% (97/123) of control subjects expressing this perspective at Month 24.

In response to the question, “How satisfied are you with the relief of pain in your neck, shoulder, arms and hands following the operation,” approximately three-fifths of subjects in both groups indicated that they were “Extremely Satisfied” at Week 6. Satisfaction appeared to improve with time, and 71.9% (179/249) of investigational subjects and 70.7% (87/123) of control subjects reported being “Extremely Satisfied” at Month 24.

In response to the question, “How satisfied are you with the ability to do housework, yard work or job following the operation,” approximately half of subjects in both groups indicated that they were “Extremely Satisfied” at Week 6. Satisfaction appeared to improve with time, and 74.7% (186/249) of investigational subjects and 69.9% (86/123) of control subjects reported being “Extremely Satisfied” at Month 24.

In response to the question, “How satisfied are you with strength in your shoulders, arms and hands following the operation,” approximately half of subjects in both groups indicated that they were “Extremely Satisfied” at Week 6. Satisfaction appeared to improve with time, and 66.7% (166/249) of investigational subjects and 61.0% (75/123) of control subjects reported being “Extremely Satisfied” at Month 24.

Lastly, in response to the question, “How satisfied are you with the feeling in your shoulders, arms and hands following the operation,” slightly more than half of subjects in both groups indicated that they were “Extremely Satisfied” at Week 6. Satisfaction appeared to improve with time, and 65.1% (162/249) of investigational subjects and 62.6% (77/123) of control subjects reported being “Extremely Satisfied” at Month 24.

### ***Device Condition***

Based upon the radiographic data, device condition was assessed at each timepoint. All devices at the superior level in both groups were assessed to be intact (i.e., no evidence of device disassembly, fracture, or loosening), with the exception of one (1) device classified as loose (i.e., new or progressive radiolucency at the implant-bone interface indicating a loss of fixation, or clear presence of device migration or toggle) at Month 6 in the investigational group, two (2) devices classified as loose at Month 12 in the investigational group, and one (1) device classified as loose at Month 24 in the investigational group.

**Table 29** identifies the device condition classification at the inferior level in both groups. The vast majority of devices were assessed to be intact, but a number of devices were classified as loose in both groups based upon the radiographic data. There was no evidence of device disassembly or fracture in either group. In some cases, an assessment was deemed indeterminate based upon the inability to make an assessment from the available images due to technical factors, sub-optimal image quality, obscured anatomy, obstructed view, or other imaging artifacts.

**Table 29: Device Condition - Inferior Index Level (mITT Analysis Set N=433, Excluding subjects with SSIs at Index Level)**

	PreOp						Week 06						Month 3					
	prodisc® C			Mobi C			prodisc® C			Mobi C			prodisc® C			Mobi C		
	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%
Intact	0	0	.	0	0	.	283	280	98.9%	139	137	98.6%	283	282	99.6%	137	137	100.0%
Disassembled	0	0	.	0	0	.	283	0	0.0%	139	0	0.0%	283	0	0.0%	137	0	0.0%
Fractured	0	0	.	0	0	.	283	0	0.0%	139	0	0.0%	283	0	0.0%	137	0	0.0%
Loose	0	0	.	0	0	.	283	0	0.0%	139	0	0.0%	283	0	0.0%	137	0	0.0%
Indeterminate	0	0	.	0	0	.	283	3	1.1%	139	2	1.4%	283	1	0.4%	137	0	0.0%
Unable to assess	0	0	.	0	0	.	283	0	0.0%	139	0	0.0%	283	0	0.0%	137	0	0.0%
Not Applicable	0	0	.	0	0	.	283	0	0.0%	139	0	0.0%	283	0	0.0%	137	0	0.0%
Not Required	0	0	.	0	0	.	283	0	0.0%	139	0	0.0%	283	0	0.0%	137	0	0.0%
Subjects censored at Index level secondary surgical interventions. Source: Table Qualitative Radiography mITT.sas; Analyzed: 26MAR2025																		
	Month 6						Month 12						Month 24					
	prodisc® C			Mobi C			prodisc® C			Mobi C			prodisc® C			Mobi C		
	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%
Intact	284	281	98.9%	138	137	99.3%	283	280	98.9%	130	129	99.2%	247	244	98.8%	126	126	100.0%
Disassembled	284	0	0.0%	138	0	0.0%	283	0	0.0%	130	0	0.0%	247	0	0.0%	126	0	0.0%
Fractured	284	0	0.0%	138	0	0.0%	283	0	0.0%	130	0	0.0%	247	0	0.0%	126	0	0.0%
Loose	284	0	0.0%	138	0	0.0%	283	1	0.4%	130	0	0.0%	247	1	0.4%	126	0	0.0%
Indeterminate	284	3	1.1%	138	1	0.7%	283	2	0.7%	130	1	0.8%	247	2	0.8%	126	0	0.0%
Unable to assess	284	0	0.0%	138	0	0.0%	283	0	0.0%	130	0	0.0%	247	0	0.0%	126	0	0.0%
Not Applicable	284	0	0.0%	138	0	0.0%	283	0	0.0%	130	0	0.0%	247	0	0.0%	126	0	0.0%
Not Required	284	0	0.0%	138	0	0.0%	283	0	0.0%	130	0	0.0%	247	0	0.0%	126	0	0.0%
Subjects censored at Index level secondary surgical interventions. Source: Table Qualitative Radiography mITT.sas; Analyzed: 26MAR2025																		

**Device Migration**

Based upon the radiographic data, device migration was assessed at each timepoint. All devices at the superior level in both groups were assessed to have no evidence of migration, with the exception of two (1) devices detected to have migrated (i.e., presence of AP or lateral change in implant position greater than or equal to 3mm) at Month 6 in the investigational group, three (3) devices detected to have migrated at Month 12 in the investigational group, and two (2) device detected to have migrated at Month 24 in the investigational group. There were a few devices in both groups at Week 6 where device migration could not be assessed due to missing images or inadequate field of view. All devices at the inferior level in both groups were assessed to have no evidence of migration, although there were a few cases at all post-operative timepoints in both groups that were indeterminate or could not be assessed.

### ***Device Protrusion***

Based upon the radiographic data, device protrusion was assessed at each timepoint. Most devices at the superior level in both groups were assessed to have no protrusion (i.e., no device migration beyond the margin of the disc space), with some devices having Grade I protrusion (i.e., less than or equal to 10% protrusion beyond the margin of the disc space), and a few devices with Grade II protrusion (i.e., 11-25% protrusion beyond the margin of the disc space), at the post-operative timepoints. At Month 24, 93.9% (232/247) of the investigational devices and 88.9% (112/126) of the control devices were assessed to have no protrusion, 4.9% (12/247) of the investigation devices and 10.3% (13/126) of the control devices were assessed to have Grade I protrusion, and 1.2% (3/247) of the investigational devices and 0.8% (1/126) of the control devices were assessed to have Grade II protrusion.

Similarly, most devices at the inferior level in both groups were assessed to have no protrusion, with some devices having Grade I protrusion, a few devices with Grade II protrusion, and a few devices determined to be indeterminate (i.e., an assessment could not be made from the available images due to technical factors, sub-optimal image quality, obscured anatomy, obstructed view or other imaging artifacts), at the post-operative timepoints. At Month 24, 94.7% (234/247) of the investigational devices and 91.3% (115/126) of the control devices were assessed to have no protrusion, 5.3% (13/247) of the investigation devices and 7.9% (10/126) of the control devices were assessed to have Grade I protrusion, and 0.8% (1/126) of the control devices were assessed to have Grade II protrusion.

### ***Device Subsidence***

Based upon the radiographic data, device subsidence was evaluated at each timepoint. Most devices at the superior level in both groups were assessed to have no subsidence (i.e., no evidence of cranial or caudal subsidence of the implant greater than or equal to 2mm), with 97.6% (241/247) of investigational devices and 100% (126/126) of control devices assessed to have no subsidence at Month 24.

Similarly, most devices at the inferior level in both groups were assessed to have no evidence of subsidence, with 96.0% (237/247) of investigational devices, 100% (126/126) of control devices assessed to have no subsidence, and 1.2% (3/247) of investigational devices rated as indeterminate, at Month 24.

### ***Heterotopic Ossification***

Based upon the radiographic data, HO was evaluated at each timepoint. The following definitions were used: none – no evidence of osteophyte formation or heterotopic ossification; Class I – HO is present in islands of bone within soft tissue but is not influencing the ROM of the vertebral motion segment. Bone is not between the planes formed by the two vertebral endplates; Class II – HO or post-operative osteophytes are present between the two planes formed by the vertebral endplates but are not significantly blocking or articulating between adjacent vertebral endplates or osteophytes; Class III – The ROM of the vertebral endplates is blocked by the formation of HO and/or post-operative osteophytes on flexion-extension or lateral bending radiographs; and, Class IV – An apparent continuous connection of bone exists across the adjacent vertebral endplates caused by bridging osteophytes or HO.

**Table 30** identifies the findings related to HO at each timepoint at the superior level. There is increasing progression of HO over time, with Class II HO being the predominant type at later timepoints. A total of 42.9% (106/247) of investigational devices and 59.5% (75/126) of control devices were assessed to have Class II HO at Month 24.

**Table 30: Heterotopic Ossification – Superior Index Level (mITT Analysis Set N=433, Excluding subjects with SSIs at Index Level)**

	PreOp						Week 06						Month 3					
	prodisc® C			Mobi C			prodisc® C			Mobi C			prodisc® C			Mobi C		
	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%
None	0	0	.	0	0	.	283	251	88.7%	139	115	82.7%	283	230	81.3%	137	97	70.8%
Class I	0	0	.	0	0	.	283	17	6.0%	139	16	11.5%	283	27	9.5%	137	21	15.3%
Class II	0	0	.	0	0	.	283	14	4.9%	139	8	5.8%	283	23	8.1%	137	17	12.4%
Class III	0	0	.	0	0	.	283	1	0.4%	139	0	0.0%	283	3	1.1%	137	2	1.5%
Class IV	0	0	.	0	0	.	283	0	0.0%	139	0	0.0%	283	0	0.0%	137	0	0.0%
Indeterminate	0	0	.	0	0	.	283	0	0.0%	139	0	0.0%	283	0	0.0%	137	0	0.0%
Unable to assess	0	0	.	0	0	.	283	0	0.0%	139	0	0.0%	283	0	0.0%	137	0	0.0%
Not Applicable	0	0	.	0	0	.	283	0	0.0%	139	0	0.0%	283	0	0.0%	137	0	0.0%
Not Required	0	0	.	0	0	.	283	0	0.0%	139	0	0.0%	283	0	0.0%	137	0	0.0%

Subjects censored at Index level secondary surgical interventions.  
Source: Table Qualitative Radiography mITT.sas; Analyzed: 26MAR2025

	Month 6						Month 12						Month 24					
	prodisc® C			Mobi C			prodisc® C			Mobi C			prodisc® C			Mobi C		
	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%
None	284	185	65.1%	138	71	51.4%	283	120	42.4%	130	38	29.2%	247	59	23.9%	126	20	15.9%
Class I	284	39	13.7%	138	25	18.1%	283	41	14.5%	130	16	12.3%	247	28	11.3%	126	12	9.5%
Class II	284	53	18.7%	138	38	27.5%	283	92	32.5%	130	64	49.2%	247	106	42.9%	126	75	59.5%
Class III	284	6	2.1%	138	3	2.2%	283	25	8.8%	130	11	8.5%	247	47	19.0%	126	17	13.5%
Class IV	284	1	0.4%	138	1	0.7%	283	5	1.8%	130	1	0.8%	247	7	2.8%	126	2	1.6%
Indeterminate	284	0	0.0%	138	0	0.0%	283	0	0.0%	130	0	0.0%	247	0	0.0%	126	0	0.0%
Unable to assess	284	0	0.0%	138	0	0.0%	283	0	0.0%	130	0	0.0%	247	0	0.0%	126	0	0.0%
Not Applicable	284	0	0.0%	138	0	0.0%	283	0	0.0%	130	0	0.0%	247	0	0.0%	126	0	0.0%
Not Required	284	0	0.0%	138	0	0.0%	283	0	0.0%	130	0	0.0%	247	0	0.0%	126	0	0.0%

Subjects censored at Index level secondary surgical interventions.  
Source: Table Qualitative Radiography mITT.sas; Analyzed: 26MAR2025

**Table 31** identifies the findings related to HO at each timepoint at the inferior level. Similarly, there is increasing progression of HO over time, with Class II HO being the predominant type at later timepoints. A total of 45.3% (112/247) of investigational devices and 54.0% (68/126) of control devices were assessed to have Class II HO at Month 24.

**Table 31: Heterotopic Ossification – Inferior Index Level (mITT Analysis Set N=433, Excluding subjects with SSIs at Index Level)**

	PreOp						Week 06						Month 3					
	prodisc® C			Mobi C			prodisc® C			Mobi C			prodisc® C			Mobi C		
	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%
None	0	0	.	0	0	.	283	245	86.6%	139	111	79.9%	283	222	78.4%	137	95	69.3%
Class I	0	0	.	0	0	.	283	19	6.7%	139	13	9.4%	283	28	9.9%	137	22	16.1%
Class II	0	0	.	0	0	.	283	7	2.5%	139	12	8.6%	283	17	6.0%	137	18	13.1%
Class III	0	0	.	0	0	.	283	1	0.4%	139	0	0.0%	283	2	0.7%	137	0	0.0%
Class IV	0	0	.	0	0	.	283	0	0.0%	139	0	0.0%	283	0	0.0%	137	0	0.0%
Indeterminate	0	0	.	0	0	.	283	11	3.9%	139	3	2.2%	283	14	4.9%	137	2	1.5%
Unable to assess	0	0	.	0	0	.	283	0	0.0%	139	0	0.0%	283	0	0.0%	137	0	0.0%
Not Applicable	0	0	.	0	0	.	283	0	0.0%	139	0	0.0%	283	0	0.0%	137	0	0.0%
Not Required	0	0	.	0	0	.	283	0	0.0%	139	0	0.0%	283	0	0.0%	137	0	0.0%

Subjects censored at Index level secondary surgical interventions.  
Source: Table Qualitative Radiography mITT.sas; Analyzed: 26MAR2025

	Month 6						Month 12						Month 24					
	prodisc® C			Mobi C			prodisc® C			Mobi C			prodisc® C			Mobi C		
	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%
None	284	172	60.6%	138	69	50.0%	283	120	42.4%	130	37	28.5%	247	61	24.7%	126	23	18.3%
Class I	284	47	16.5%	138	19	13.8%	283	37	13.1%	130	10	7.7%	247	25	10.1%	126	6	4.8%
Class II	284	43	15.1%	138	43	31.2%	283	89	31.4%	130	66	50.8%	247	112	45.3%	126	68	54.0%
Class III	284	9	3.2%	138	5	3.6%	283	16	5.7%	130	14	10.8%	247	28	11.3%	126	24	19.0%
Class IV	284	0	0.0%	138	0	0.0%	283	8	2.8%	130	2	1.5%	247	14	5.7%	126	3	2.4%
Indeterminate	284	13	4.6%	138	2	1.4%	283	13	4.6%	130	1	0.8%	247	7	2.8%	126	2	1.6%
Unable to assess	284	0	0.0%	138	0	0.0%	283	0	0.0%	130	0	0.0%	247	0	0.0%	126	0	0.0%
Not Applicable	284	0	0.0%	138	0	0.0%	283	0	0.0%	130	0	0.0%	247	0	0.0%	126	0	0.0%
Not Required	284	0	0.0%	138	0	0.0%	283	0	0.0%	130	0	0.0%	247	0	0.0%	126	0	0.0%

Subjects censored at Index level secondary surgical interventions.  
Source: Table Qualitative Radiography mITT.sas; Analyzed: 26MAR2025

### ***Adjacent level Disc Degeneration (Kellgren-Lawrence)***

Based upon the radiographic data, adjacent level disc degeneration (ALDD) was evaluated at each timepoint. The following scale was used: none – No degenerative changes; doubtful – Minimal osteophytosis only; minimal – Definite osteophytosis with some sclerosis of vertebral plates with slight narrowing of disk space; moderate – Marked osteophytosis with sclerosis of vertebral plates with slight narrowing of disc space; and, Severe – Large osteophytes, marked sclerosis of vertebral plates, and marked narrowing of disc space.

**Table 32** reports the findings related to ALDD at each timepoint at the superior level. There is an increase in ALDD over time in both groups. However, only 1.2% (3/247) of investigational subjects and 1.6% (2/126) of control subjects are classified to have severe ALDD at Month 24.

**Table 32: Adjacent Level DD – Superior Index Level (mITT Analysis Set N=433, Excluding subjects with SSIs at Index Level)**

	PreOp						Week 06						Month 3					
	prodisc® C			Mobi C			prodisc® C			Mobi C			prodisc® C			Mobi C		
	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%
None	0	0	.	0	0	.	283	91	32.2%	139	41	29.5%	283	81	28.6%	137	39	28.5%
Doubtful	0	0	.	0	0	.	283	81	28.6%	139	47	33.8%	283	87	30.7%	137	49	35.8%
Minimal	0	0	.	0	0	.	283	66	23.3%	139	33	23.7%	283	69	24.4%	137	31	22.6%
Moderate	0	0	.	0	0	.	283	42	14.8%	139	15	10.8%	283	42	14.8%	137	15	10.9%
Severe	0	0	.	0	0	.	283	3	1.1%	139	3	2.2%	283	4	1.4%	137	3	2.2%
Indeterminate	0	0	.	0	0	.	283	0	0.0%	139	0	0.0%	283	0	0.0%	137	0	0.0%
Unable to assess	0	0	.	0	0	.	283	0	0.0%	139	0	0.0%	283	0	0.0%	137	0	0.0%
Not Applicable	0	0	.	0	0	.	283	0	0.0%	139	0	0.0%	283	0	0.0%	137	0	0.0%
Not Required	0	0	.	0	0	.	283	0	0.0%	139	0	0.0%	283	0	0.0%	137	0	0.0%

Subjects censored at Index level secondary surgical interventions.  
Source: Table Qualitative Radiography mITT.sas; Analyzed: 26MAR2025

	Month 6						Month 12						Month 24					
	prodisc® C			Mobi C			prodisc® C			Mobi C			prodisc® C			Mobi C		
	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%
None	284	80	28.2%	138	37	26.8%	283	68	24.0%	130	31	23.8%	247	44	17.8%	126	27	21.4%
Doubtful	284	81	28.5%	138	48	34.8%	283	85	30.0%	130	46	35.4%	247	70	28.3%	126	39	31.0%
Minimal	284	76	26.8%	138	35	25.4%	283	78	27.6%	130	33	25.4%	247	83	33.6%	126	37	29.4%
Moderate	284	43	15.1%	138	15	10.9%	283	48	17.0%	130	17	13.1%	247	47	19.0%	126	19	15.1%
Severe	284	4	1.4%	138	3	2.2%	283	3	1.1%	130	3	2.3%	247	3	1.2%	126	2	1.6%
Indeterminate	284	0	0.0%	138	0	0.0%	283	1	0.4%	130	0	0.0%	247	0	0.0%	126	0	0.0%
Unable to assess	284	0	0.0%	138	0	0.0%	283	0	0.0%	130	0	0.0%	247	0	0.0%	126	2	1.6%
Not Applicable	284	0	0.0%	138	0	0.0%	283	0	0.0%	130	0	0.0%	247	0	0.0%	126	0	0.0%
Not Required	284	0	0.0%	138	0	0.0%	283	0	0.0%	130	0	0.0%	247	0	0.0%	126	0	0.0%

Subjects censored at Index level secondary surgical interventions.  
Source: Table Qualitative Radiography mITT.sas; Analyzed: 26MAR2025

**Table 33** reports the findings related to ALDD at each timepoint at the inferior level. There is a similar increase in ALDD over time in both groups. However, only 3.2% (8/247) of investigational subjects and 2.4% (3/126) of control subjects are classified to have marked ALDD at Month 24, with the caveat that 29.6% (73/247) of investigational devices and 29.4% (37/126) of control devices at Month 24 were categorized as indeterminate.

**Table 33: Adjacent Level DD – Inferior Index Level (mITT Analysis Set N=433, Excluding subjects with SSIs at Index Level)**

	PreOp						Week 06						Month 3					
	prodisc® C			Mobi C			prodisc® C			Mobi C			prodisc® C			Mobi C		
	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%
None	0	0	.	0	0	.	283	89	31.4%	139	52	37.4%	283	81	28.6%	137	44	32.1%
Doubtful	0	0	.	0	0	.	283	65	23.0%	139	26	18.7%	283	65	23.0%	137	33	24.1%
Minimal	0	0	.	0	0	.	283	15	5.3%	139	12	8.6%	283	16	5.7%	137	11	8.0%
Moderate	0	0	.	0	0	.	283	10	3.5%	139	5	3.6%	283	13	4.6%	137	5	3.6%
Severe	0	0	.	0	0	.	283	9	3.2%	139	3	2.2%	283	8	2.8%	137	3	2.2%
Indeterminate	0	0	.	0	0	.	283	95	33.6%	139	41	29.5%	283	100	35.3%	137	41	29.9%
Unable to assess	0	0	.	0	0	.	283	0	0.0%	139	0	0.0%	283	0	0.0%	137	0	0.0%
Not Applicable	0	0	.	0	0	.	283	0	0.0%	139	0	0.0%	283	0	0.0%	137	0	0.0%
Not Required	0	0	.	0	0	.	283	0	0.0%	139	0	0.0%	283	0	0.0%	137	0	0.0%

Subjects censored at Index level secondary surgical interventions.  
Source: Table Qualitative Radiography mITT.sas; Analyzed: 26MAR2025

	Month 6						Month 12						Month 24					
	prodisc® C			Mobi C			prodisc® C			Mobi C			prodisc® C			Mobi C		
	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%
None	284	74	26.1%	138	44	31.9%	283	66	23.3%	130	34	26.2%	247	53	21.5%	126	28	22.2%
Doubtful	284	68	23.9%	138	32	23.2%	283	77	27.2%	130	30	23.1%	247	71	28.7%	126	33	26.2%
Minimal	284	25	8.8%	138	12	8.7%	283	28	9.9%	130	16	12.3%	247	29	11.7%	126	16	12.7%
Moderate	284	10	3.5%	138	6	4.3%	283	14	4.9%	130	5	3.8%	247	13	5.3%	126	9	7.1%
Severe	284	9	3.2%	138	4	2.9%	283	10	3.5%	130	4	3.1%	247	8	3.2%	126	3	2.4%
Indeterminate	284	98	34.5%	138	40	29.0%	283	88	31.1%	130	41	31.5%	247	73	29.6%	126	37	29.4%
Unable to assess	284	0	0.0%	138	0	0.0%	283	0	0.0%	130	0	0.0%	247	0	0.0%	126	0	0.0%
Not Applicable	284	0	0.0%	138	0	0.0%	283	0	0.0%	130	0	0.0%	247	0	0.0%	126	0	0.0%
Not Required	284	0	0.0%	138	0	0.0%	283	0	0.0%	130	0	0.0%	247	0	0.0%	126	0	0.0%

Subjects censored at Index level secondary surgical interventions.  
Source: Table Qualitative Radiography mITT.sas; Analyzed: 26MAR2025

**Angular Motion**

Angular motion was defined as the change in angle between the adjacent endplates of the motion segment, and was calculated from lateral flexion-extension radiographs. **Table 34** reports the angular motion of the superior level for each timepoint in both groups. In addition, **Table 35** identifies the angular motion of the inferior level for each timepoint in both groups. The results for both groups, at the inferior and superior levels, suggest that no angular motion is lost over time relative to the pre-operative assessment.

**Table 34: Angular Motion Superior Index Level Over Time (mITT Analysis Set N=433, Excluding subjects with SSIs at Index Level)**

	prodisc® C						Mobi C						Group Difference*		
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	Δ	LB	UB
PreOp	286	8.43	4.45	8.40	0.00	23.90	138	9.31	4.63	9.00	0.00	24.00	-0.87	-1.74	0.06
Week 06	271	8.79	3.53	9.00	0.50	17.00	136	9.12	3.81	8.70	1.90	21.00	-0.33	-1.08	0.44
Month 03	280	8.89	3.88	9.70	1.00	19.40	137	10.99	4.45	10.80	3.20	24.80	-1.10	-1.94	-0.28
Month 06	282	10.23	4.26	10.65	0.10	22.10	138	12.11	5.08	12.40	1.20	25.10	-1.88	-2.78	-0.97
Month 12	281	9.93	4.67	10.30	0.10	23.70	129	12.04	5.41	12.20	0.90	24.30	-2.11	-3.14	-1.11
Month 24	247	9.36	4.96	9.40	0.10	21.90	124	11.54	5.45	11.70	0.10	25.10	-2.20	-3.33	-1.13

Subjects censored at Index level secondary surgical interventions.  
 \*Device group mean differences and 95% Credible Intervals.  
 Source: Tables Quantitative Radiography - mITT.sas; Analyzed: 18MAR2025

**Table 35: Angular Motion Inferior Index Level Over Time (mITT Analysis Set N=433, Excluding subjects with SSIs at Index Level)**

	prodisc® C						Mobi C						Group Difference*		
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	Δ	LB	UB
PreOp	265	6.96	3.84	6.60	0.00	18.00	131	7.41	4.11	7.10	0.00	16.90	-0.44	-1.21	0.40
Week 06	248	8.18	4.08	8.00	0.20	19.00	129	7.06	4.27	6.50	0.00	18.40	1.13	0.27	2.04
Month 03	254	8.97	4.25	8.80	0.10	20.00	125	8.45	4.57	7.80	0.70	19.80	0.52	-0.40	1.44
Month 06	255	9.21	4.41	8.90	0.10	20.30	126	9.88	5.03	9.25	1.10	21.40	-0.68	-1.66	0.28
Month 12	248	8.90	4.72	8.80	0.00	20.10	122	9.32	5.06	8.90	0.70	21.40	-0.41	-1.45	0.63
Month 24	227	8.44	4.86	8.00	0.20	22.20	114	9.39	5.52	9.05	1.10	20.70	-0.97	-2.14	0.13

Subjects censored at Index level secondary surgical interventions.  
 \*Device group mean differences and 95% Credible Intervals.  
 Source: Tables Quantitative Radiography - mITT.sas; Analyzed: 18MAR2025

**Translational Motion**

Translational Motion was defined as displacement of the posterior-inferior corner of the superior vertebra in a direction defined parallel to the superior endplate of the inferior vertebra. **Table 36** reports the translational motion of the superior level for each timepoint in both groups. Similarly, **Table 37** identifies the translational motion of the inferior level for each timepoint in both groups. Translational motion at the superior and inferior levels modestly increased at Week 6, and the increase was mostly maintained at later timepoints. The mean change from baseline in both groups was less than 1mm for all post-operative timepoints.

**Table 36: Translational Motion Superior Index Level Over Time [mm] (mITT Analysis Set N=433, Excluding subjects with SSIs at Index Level)**

	prodisc® C						Mobi C						Group Difference*		
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	Δ	LB	UB
PreOp	285	1.07	0.66	1.00	0.00	3.40	138	1.25	0.76	1.15	0.00	3.50	-0.18	-0.32	-0.04
Week 06	270	1.17	0.56	1.10	0.00	4.40	136	1.51	0.72	1.40	0.20	4.00	-0.34	-0.48	-0.22
Month 03	279	1.29	0.57	1.20	0.00	3.00	137	1.81	0.82	1.80	0.30	4.20	-0.52	-0.66	-0.39
Month 06	281	1.32	0.60	1.30	0.00	3.10	138	2.01	0.97	1.95	0.00	5.20	-0.69	-0.84	-0.54
Month 12	280	1.27	0.66	1.30	0.00	3.10	129	1.97	0.99	2.00	0.00	5.00	-0.70	-0.86	-0.53
Month 24	247	1.16	0.67	1.10	0.00	2.90	124	1.83	0.93	1.80	0.00	4.90	-0.68	-0.85	-0.52

Subjects censored at Index level secondary surgical interventions.  
 \*Device group mean differences and 95% Credible Intervals.  
 Source: Tables Quantitative Radiography - mITT.sas; Analyzed: 18MAR2025

**Table 37: Translational Motion Inferior Index Level Over Time [mm] (mITT Analysis Set N=433, Excluding subjects with SSIs at Index Level)**

	prodisc® C						Mobi C						Group Difference*		
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	Δ	LB	UB
PreOp	264	0.58	0.44	0.50	0.00	2.40	131	0.69	0.56	0.60	0.00	2.90	-0.10	-0.20	0.00
Week 06	247	1.05	0.63	1.00	0.00	5.20	129	0.94	0.63	0.80	0.00	2.90	0.11	-0.02	0.26
Month 03	253	1.13	0.60	1.10	0.00	3.30	125	1.14	0.73	1.00	0.00	3.40	-0.01	-0.15	0.13
Month 06	254	1.14	0.61	1.10	0.00	3.40	126	1.33	0.78	1.20	0.10	3.70	-0.19	-0.33	-0.04
Month 12	247	1.11	0.64	1.10	0.00	3.40	122	1.23	0.78	1.10	0.00	3.70	-0.12	-0.27	0.03
Month 24	227	1.01	0.62	1.00	0.00	2.80	114	1.20	0.80	1.05	0.00	3.50	-0.19	-0.35	-0.04

Subjects censored at Index level secondary surgical interventions.  
 \*Device group mean differences and 95% Credible Intervals.  
 Source: Tables Quantitative Radiography - mITT.sas; Analyzed: 18MAR2025

**Global Range of Motion**

Global ROM (GROM) was calculated by subtracting the C2-C7 angle in flexion from the C2-C7 angle in extension measured between the inferior endplate of C2 and the inferior endplate of C7.

Table 38 identifies the calculated GROM at the pre-operative and post-operative timepoints. After Week 6, the mean GROM was calculated as increasing relative to the pre-operative timepoint. The mean GROM was calculated as 46.96 degrees in the investigational group and 49.21 degrees in the control group at Month 24, relative to a mean GROM of 43.88 degrees in the investigational group and 45.57 degrees in the control group pre-operatively, suggesting a modestly higher GROM out to 24 months after surgery in both groups.

**Table 38: Global Range of Motion (degrees) Over Time (mITT Analysis Set N=433, Excluding subjects with SSIs at Index Level)**

	prodisc® C						Mobi C						Group Difference*		
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	Δ	LB	UB
PreOp	258	43.88	13.69	43.15	6.50	84.80	129	45.57	15.51	45.60	7.30	95.30	-1.67	-4.55	1.28
Week 06	243	42.32	12.13	41.90	8.90	78.70	127	39.85	12.93	40.60	7.70	73.90	2.50	-0.21	5.14
Month 03	246	45.88	13.45	46.20	16.10	85.30	122	46.29	13.13	46.15	14.50	74.90	-0.38	-3.23	2.48
Month 06	249	47.76	13.58	48.00	10.20	85.40	124	51.32	15.66	50.05	16.50	94.30	-3.56	-6.53	-0.47
Month 12	241	47.74	14.60	48.00	16.70	92.40	119	50.33	14.66	48.20	15.60	98.60	-2.58	-5.80	0.59
Month 24	220	46.96	13.40	47.20	7.60	85.00	113	49.21	15.55	49.10	17.40	94.00	-2.30	-5.31	1.11

Subjects censored at Index level secondary surgical interventions.  
 \*Device group mean differences and 95% Credible Intervals.  
 Source: Tables Quantitative Radiography - mITT.sas; Analyzed: 18MAR2025

**Average Disc Height**

Disc height was measured between the anterior-inferior (posterior-inferior) corner of the superior vertebra and the corresponding corner of the inferior vertebra. Average disc height was calculated as the simple mean of the anterior and posterior disc heights.

**Table 39** reports the average disc height over time at the superior level. The mean average disc height increased post-operatively in both groups and was maintained over time. The mean average disc height was calculated as 5.29mm in the investigational group and 5.50mm in the control group at Month 24. **Table 40** reports the average disc height over time at the inferior level. The mean average disc height increased post-operatively in both groups and was maintained over time. The mean average disc height was found to be 5.24mm in the investigational group and 5.51mm in the control group at Month 24.

**Table 39: Average Disc Height Superior Index Level Over Time (mITT Analysis Set N=433, Excluding subjects with SSIs at Index Level)**

	prodisc® C						Mobi C						Group Difference*		
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	Δ	LB	UB
PreOp	287	3.03	0.80	3.00	0.80	5.10	137	3.12	0.85	3.10	1.30	5.30	-0.09	-0.25	0.08
Post-Op	288	5.60	0.67	5.60	2.30	8.00	139	5.67	0.65	5.60	4.20	8.00	-0.07	-0.19	0.07
Week 06	282	5.56	0.68	5.60	2.30	8.00	139	5.57	0.65	5.60	3.90	8.00	-0.01	-0.15	0.13
Month 03	282	5.53	0.68	5.60	2.20	8.00	136	5.55	0.65	5.60	3.90	8.00	-0.02	-0.15	0.12
Month 06	283	5.49	0.71	5.50	2.30	8.00	138	5.53	0.65	5.50	3.70	7.90	-0.04	-0.17	0.11
Month 12	282	5.43	0.74	5.50	1.90	7.90	130	5.49	0.63	5.50	3.50	7.70	-0.06	-0.22	0.08
Month 24	247	5.29	0.84	5.40	1.90	7.90	125	5.50	0.65	5.50	3.70	7.70	-0.22	-0.40	-0.06

Subjects censored at Index level secondary surgical interventions.  
 \*Device group mean differences and 95% Credible Intervals.  
 Source: Tables Quantitative Radiography - mITT.sas; Analyzed: 18MAR2025

**Table 40: Average Disc Height Inferior Index Level Over Time (mITT Analysis Set N=433, Excluding subjects with SSIs at Index Level)**

	prodisc® C						Mobi C						Group Difference*		
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	Δ	LB	UB
PreOp	274	3.17	0.77	3.10	1.30	5.40	132	3.19	0.86	3.10	1.60	6.00	-0.02	-0.19	0.15
Post-Op	275	5.48	0.60	5.60	3.80	7.00	136	5.63	0.72	5.70	3.00	7.60	-0.14	-0.27	-0.01
Week 06	272	5.46	0.60	5.50	3.70	7.00	137	5.54	0.72	5.60	3.00	7.60	-0.08	-0.22	0.05
Month 03	265	5.44	0.60	5.50	3.80	6.90	134	5.52	0.74	5.50	2.80	7.60	-0.09	-0.22	0.05
Month 06	268	5.42	0.60	5.50	3.60	6.80	137	5.53	0.71	5.60	3.00	7.50	-0.12	-0.24	0.02
Month 12	272	5.36	0.62	5.40	3.50	6.80	128	5.52	0.72	5.60	3.00	7.50	-0.17	-0.31	-0.03
Month 24	237	5.24	0.72	5.30	2.70	6.80	122	5.51	0.71	5.55	3.10	7.50	-0.28	-0.42	-0.11

Subjects censored at Index level secondary surgical interventions.  
 \*Device group mean differences and 95% Credible Intervals.  
 Source: Tables Quantitative Radiography - mITT.sas; Analyzed: 18MAR2025

### Disc Angle

Disc angle was measured as the angle formed between the endplates of adjacent vertebrae. A disc angle greater than 0 degrees corresponds to local lordosis, while a disc angle less than 0 degrees corresponds to local kyphosis.

**Table 41** reports the disc angle over time at the superior level. The mean disc angle increased post-operatively in both groups and was maintained over time. The mean disc angle was calculated as 6.76 degrees in the investigational group and 8.53 degrees in the control group at Month 24. **Table 42** reports the disc angle over time at the inferior level. The mean disc angle increased post-operatively in both groups and was maintained over time. The mean disc angle was found to be 4.88 degrees in the investigational group and 6.10 degrees in the control group at Month 24.

**Table 41: Disc Angle Superior Index Level Over Time (mITT Analysis Set N=433, Excluding subjects with SSIs at Index Level)**

	prodisc® C						Mobi C						Group Difference*		
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	Δ	LB	UB
PreOp	288	2.03	4.17	1.95	-10.60	12.20	137	2.44	4.46	2.70	-9.40	11.60	-0.40	-1.26	0.43
Post-Op	289	6.97	4.71	7.30	-8.80	18.00	139	8.03	5.00	8.50	-4.20	19.80	-1.05	-1.97	-0.09
Week 06	283	7.07	4.75	7.00	-7.20	17.60	139	8.43	5.44	8.50	-5.00	20.40	-1.36	-2.41	-0.36
Month 03	283	7.04	4.76	7.30	-7.00	17.30	136	8.24	5.58	8.25	-5.40	25.10	-1.19	-2.21	-0.20
Month 06	284	6.79	4.76	7.15	-7.70	18.30	138	8.31	5.68	8.50	-4.60	22.30	-1.53	-2.54	-0.51
Month 12	283	6.68	4.89	7.20	-9.00	17.50	130	8.69	5.95	9.30	-3.80	25.50	-2.01	-3.07	-0.90
Month 24	247	6.76	5.02	6.90	-10.50	17.30	125	8.53	5.92	8.90	-3.30	25.50	-1.80	-2.98	-0.70

Subjects censored at Index level secondary surgical interventions.  
 \*Device group mean differences and 95% Credible Intervals.  
 Source: Tables Quantitative Radiography - mITT.sas; Analyzed: 18MAR2025

**Table 42: Disc Angle Inferior Index Level Over Time (mITT Analysis Set N=433, Excluding subjects with SSIs at Index Level)**

	prodisc® C						Mobi C						Group Difference*		
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	Δ	LB	UB
PreOp	275	2.44	4.06	2.60	-10.00	15.90	132	3.61	3.78	3.55	-5.10	14.10	-1.17	-1.95	-0.33
Post-Op	276	4.77	4.69	4.65	-11.90	18.80	136	5.95	4.93	6.10	-7.50	16.10	-1.17	-2.09	-0.21
Week 06	273	5.05	4.80	5.00	-10.70	20.00	137	6.04	5.12	6.60	-8.60	17.30	-0.98	-1.98	0.06
Month 03	266	5.09	4.75	4.90	-10.10	18.90	134	5.84	5.09	6.60	-8.60	15.40	-0.74	-1.79	0.21
Month 06	269	5.09	4.67	4.90	-7.70	18.00	137	5.90	5.00	6.20	-6.70	16.30	-0.81	-1.77	0.16
Month 12	273	5.02	4.81	4.60	-7.80	18.80	128	6.11	5.31	7.10	-7.90	16.20	-1.08	-2.14	-0.06
Month 24	237	4.88	4.67	4.90	-8.50	18.90	122	6.10	5.28	6.70	-6.60	16.20	-1.24	-2.24	-0.15

Subjects censored at Index level secondary surgical interventions.  
 \*Device group mean differences and 95% Credible Intervals.  
 Source: Tables Quantitative Radiography - mITT.sas; Analyzed: 18MAR2025

**3. Subgroup Analyses**

The study was not specifically powered for any subgroup analyses.

**4. Pediatric Extrapolation**

In this premarket application, existing clinical data were not leveraged to support approval of a pediatric patient population.

**XI. Financial Disclosure**

The Financial Disclosure by Clinical Investigators regulation (21 CFR 54) requires applicants who submit a marketing application to include certain information concerning the compensation to, and financial interests and arrangement of, any clinical investigator conducting clinical studies covered by the regulation. The pivotal clinical study included 37 principal investigators and 47 sub-investigators of which none were full-time or part-time employees of the sponsor and five (5) sub-investigators had disclosable financial interests/arrangements as defined in 21 CFR 54.2(a), (b), (c) and (f), and described below:

- Compensation to the investigator for conducting the study where the value could be influenced by the outcome of the study: *0 Investigators*
- Significant payment of other sorts: *0 Investigators*
- Proprietary interest in the product tested held by the investigator: *0 Investigators*
- Significant equity interest held by investigator in sponsor of covered study: *0 Investigators*

Centinel Spine has adequately disclosed the financial interest/arrangements with clinical investigators. Statistical analyses were conducted by FDA to determine whether the financial

interests/arrangements had any impact on the clinical study outcome. The information provided does not raise any questions about the reliability of the data.

## **XII. PANEL RECOMMENDATIONS**

In accordance with the provisions of section 515(c)(2) of the Act as amended by the Safe Medical Devices Act of 1990, this PMA Supplement was not referred to the Orthopaedic and Rehabilitation Devices Panel, an FDA advisory committee, for review and recommendation because the information in the PMA Supplement substantially duplicates information previously reviewed by this panel.

## **XIII. CONCLUSIONS DRAWN FROM THE PRECLINICAL AND CLINICAL STUDIES**

### **A. Effectiveness Conclusions**

A total of 480 subjects were randomized in this clinical trial. Following randomization, a total of 47 subjects were randomized but not treated, leaving 433 subjects in the mITT Analysis Set. The mITT Analysis Set consisted of 293 subjects in the prodisc® C SK and prodisc® C Vivo group, and 140 subjects in the Mobi-C (control) group. The mITT Analysis Set was used to test the non-inferiority hypothesis in this study.

Overall success was defined based on a primary composite endpoint which included the following components: a clinically meaningful improvement in NDI (i.e., at least 15 points) at Month 24; maintenance or improvement in neurological status at Month 24; lack of SSIs; and, absence of major device-related AEs defined as radiographic failure, neurological failure, or failure by AE as adjudicated by the CEC.

The overall success rate for the investigational group was 87.1% (221/253) as compared to a success rate of 83.7% (107/127) for the control group. The study's pre-specified success criterion required this probability to exceed 96.7% to declare success, which was achieved in this analysis.

A secondary supporting sensitivity analysis of the primary endpoint was performed for the PP Analysis Set (which per the applicant's original protocol, was the primary analysis population). The results were similar, with a success rate of 88.7% (219/246) as compared to a success rate of 84.0% (104/123) for the control group. Lastly, a tipping point analysis to consider the impact of missing data returned a robust result where the results were tipped only 19.5% of the time. Therefore, non-inferiority between the investigational and control groups was demonstrated.

In conclusion, the study data indicate that at Month 24, the prodisc® C SK and prodisc® C Vivo are at least as effective as the Mobi-C (control), for the patient population and indications studied in this investigation, in terms of overall success according to the primary composite endpoint and provides a reasonable assurance of effectiveness.

## **B. Safety Conclusions**

In the ITT Analysis Set, comparable rates of AEs occurred in the investigational group (78.5% - 252/321) and control group (78.6% - 125/159). SAEs that were considered “definitely” device-related were also comparable between the two groups, where 1.6% (5/321) of investigational subjects had “definitely” device-related SAEs, while 1.9% (3/159) control of subjects had “definitely” device-related SAEs. A total of 9 subjects experienced an SSI in the investigational group, while 6 subjects had a SSI in the control group.

In conclusion, the clinical study results demonstrate that the prodisc® C SK and prodisc® C Vivo are at least as safe as the Mobi-C (control), for the patient population and indications studied and provides a reasonable assurance of safety.

## **C. Benefit-Risk Determination**

The probable benefits of the prodisc® C SK and prodisc® C Vivo are based on data collected in the clinical study conducted to support PMA approval. The clinical study demonstrated several benefits of the subject device through Month 24.

- The benefit of the subject device was evaluated in terms of clinically meaningful improvement in function (as measured by an improvement in NDE of at least 15 points) at Month 24. The investigational subjects experienced a comparable level of NDI improvement (93.9% - 229/244) as compared to the control subjects (90.1% - 109/121) at Month 24.
- In terms of improvement in neck pain (as measured by a 20mm improvement in pain on a 100mm VAS as compared to baseline) at Month 24, investigational subjects demonstrated a comparable level of change (88.1% - 214/243) as compared to control subjects (86.9% - 106/122).
- In terms of improvement in right arm pain (as measured by a 20mm improvement in pain on a 100mm VAS as compared to baseline) at Month 24, investigational subjects demonstrated a comparable level of change (65.8% - 160/243) as compared to control subjects (68.0% - 83/122).
- In terms of improvement in left arm pain (as measured by a 20mm improvement in pain on a 100mm VAS as compared to baseline) at Month 24, investigational subjects demonstrated a comparable level of change (66.3% - 161/243) as compared to control subjects (62.3% - 76/122).
- Evaluating the change in GROM relative to baseline, the mean change at Month 24 was 2.56 degrees for the investigational group, and the mean change at Month 24 was 4.32 degrees for the control group, indicating a comparable level of improvement post-operatively.
- The subject’s perception of their benefit and risk was indirectly measured by administering the question, “How satisfied are you with the results of your neck operation?” A total of 81.1% (202/249) of investigational subjects and 78.9% (97/123) of control subjects

responded that they were “extremely satisfied”, indicating a comparable level of positive response from the patient perspective regarding the operative procedure.

The probable risks of the device are based on data collected in a clinical study conducted to support PMA approval. The investigational group experienced comparable AE and SAE rates as compared to the control group as described above. A total of 9 subjects experienced an SSI in the investigational group, while 6 subjects had an SSI in the control group; this is comparable given the nearly double sample size in the investigational group.

Additional factors considered in determining benefits and risks for the subject device include limitations of the clinical study design, including the inability to mask subjects to their treatment assignment, reliance on subjective endpoints, and subjectivity in AE classification.

Patient perspectives considered during this review include:

Neck Disability Index (NDI)

Visual Analog Scale (VAS) for Neck Pain, Left Arm Pain, Right Arm Pain

Short Form 12 (SF-12) Physical Component Scores (PCS) and Mental Component Scores (MCS)

In conclusion, given the available information above, the data support that, for reconstruction of the disc from C3-C7 following discectomy at one level or two contiguous levels for intractable radiculopathy (arm pain and/or a neurological deficit) with or without neck pain, or myelopathy due to abnormality localized to the level of the disc space and at least one of the following conditions confirmed by radiographic imaging (CT, MRI, X-rays): herniated nucleus pulposus, spondylosis (defined by the presence of osteophytes), and/or visible loss of disc height as compared to adjacent levels as outlined above in the Indications for Use, the probable benefits of the prodisc® C SK and prodisc® C Vivo outweigh the probable risks to health through Month 24.

#### **D. Overall Conclusions**

The non-clinical and clinical data in this FDA marketing application support the reasonable assurance of safety and effectiveness of the prodisc® C SK and prodisc® C Vivo when used in accordance with the indications for use. Based on the clinical study results, it is reasonable to conclude that the clinical benefits of the use of the prodisc® C SK and prodisc® C Vivo in terms of improvement in pain and disability, and the potential for motion preservation, outweigh the risks, both in terms of the risks associated with the prodisc® C SK and prodisc® C Vivo and surgical procedure when used in the indicated population in accordance with the directions for use, and as compared to the Mobi-C control treatment in the same indicated population.

#### **XIV. CDRH DECISION**

CDRH issued an approval order on October 10, 2025.

The applicant’s manufacturing facilities have been inspected and found to be in compliance with the device Quality System (QS) regulation (21 CFR 820).

**XV. APPROVAL SPECIFICATIONS**

Directions for use: See device labeling.

Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, Precautions, and Adverse Events in the device labeling.

Post-approval Requirements and Restrictions: See approval order.