SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name:	Artificial Cervical Disc
Device Trade Name:	BAGUERA® C Cervical Disc Prosthesis
Device Product Code:	MJO
Applicant's Name and Address:	Spineart USA, Inc. 23332 Mill Creek Drive, Suite 150 Laguna Hills, California 92653
Date of Panel Recommendation:	None
Premarket Approval Application (PMA) Number:	P250042
Date of FDA Notice of Approval:	August 10, 2026

II. INDICATIONS FOR USE

The BAGUERA® C Cervical Disc Prosthesis is indicated for use in skeletally mature patients for reconstruction of the disc at one or two contiguous levels from C3-C7 following single-level or two-contiguous-level discectomy for intractable radiculopathy (arm pain and/or a neurological deficit) with or without neck pain, or myelopathy due to a single-level or two-contiguous-level abnormality localized to the level of the disc space and manifested by at least one of the following conditions confirmed by radiographic imaging (e.g., X-rays, computed tomography (CT), magnetic resonance imaging (MRI)): herniated nucleus pulposus, spondylosis (defined by the presence of osteophytes), and/or visible loss of disc height as compared to adjacent levels. Patients receiving the BAGUERA® C Cervical Disc Prosthesis should have failed at least six weeks of non-operative treatment or have the presence of progressive symptoms (e.g., numbness or tingling) prior to implantation. The BAGUERA® C Cervical Disc Prosthesis is implanted via an open anterior approach.

III. CONTRAINDICATIONS

The BAGUERA® C Cervical Disc Prosthesis should not be implanted in patients with the following conditions:

- Compromised vertebral bodies at the index level(s) due to previous trauma to the cervical spine or to significant cervical anatomical deformity (e.g., scoliosis) or disease (e.g., ankylosing spondylitis, rheumatoid arthritis);
- Facet joint disease or degeneration;
- Marked cervical instability on resting lateral or flexion/extension radiographs demonstrated by translation greater than or equal to 3.5mm and/or greater than 11 degrees of angular difference from either adjacent segments;
- Active systemic or local infection;
- Allergy or sensitivity to the implant materials (titanium, aluminum, vanadium or polyethylene);
- Osteoporosis or osteopenia defined as dual energy x-ray absorptiometry (DEXA) scan of the spine with a bone density T-score less than or equal to -1.5.

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the BAGUERA® C Cervical Disc Prosthesis labeling.

V. DEVICE DESCRIPTION

The BAGUERA® C Cervical Disc Prosthesis is an artificial cervical disc that is inserted into the intervertebral disc space at one or two contiguous levels using an anterior approach. It is manufactured from titanium (Ti-6Al-4V alloy per ASTM F136 and ISO 5832-3) endplates and a mobile, Vitamin E blended crosslinked high-density polyethylene (AO-XLPE GUR® 1020E per ASTM F648 and ASTM F2695-12) core. The titanium endplates have a plasma-sprayed titanium coating per ISO 13179-1. The articulating surface of the endplates is coated with a non-permeable, diamond-like carbon (DLC) film, deposited by plasma-activated chemical vapor deposition (PACVD). The device is pictured in Figure V-1 below.

Figure V-1 BAGUERA® C Cervical Disc Prosthesis: assembly (left), and mid-sagittal section (right)

The final implant is pre-mounted on a disposable radiolucent fork to allow the device to remain in the assembled configuration during the surgical procedure while enabling fluoroscopic controls of the implant positioning.

The BAGUERA® C Cervical Disc Prosthesis product range is based on a homothetic shape designed around the AO-XLPE core, so that the weight-bearing surface withstanding the compressive load is intended to remain constant regardless of the implant size. Note that the AO-XLPE nucleus is the same shape and size for the complete product range. With its hemi-spherical domed shape, the guided nucleus is designed to enable the functional spine unit to have an adaptive center of rotation and is intended to allow 6 degrees of freedom.

In addition, the AO-XLPE nucleus and the endplates are designed to achieve 8° lateral bending and flexion/extension, resulting in 16° Range of Motion (ROM). The axial rotation is limited by the anatomical structures and not constrained by the prosthesis. These ranges of motion are intended to permit the patient's anatomy to determine actual range of motion without imposing an artificial limit that may be restrictive to the patient's kinematic profile. The maximum range of motion in vivo will be dictated by the patient's anatomical boundaries or the device limits, whichever is smaller.

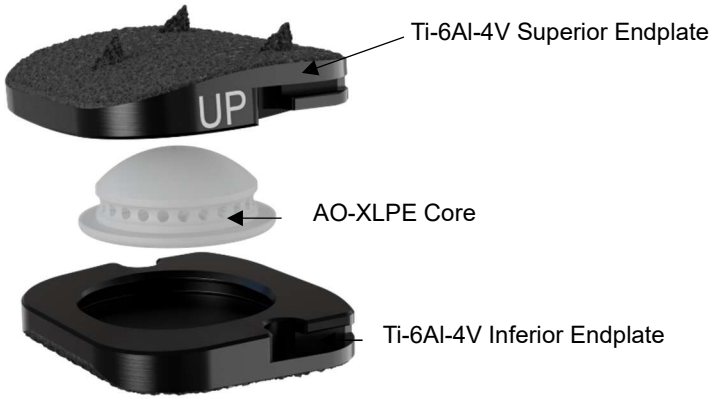

Figure V-2 Exploded view of the BAGUERA® C Cervical Disc Prosthesis

Superior and inferior endplates are available in three footprints (Small, Medium, Large), three thicknesses resulting in three different heights (5mm, 6mm, 7mm) as outlined in Figure V-3 and Table 1 below.

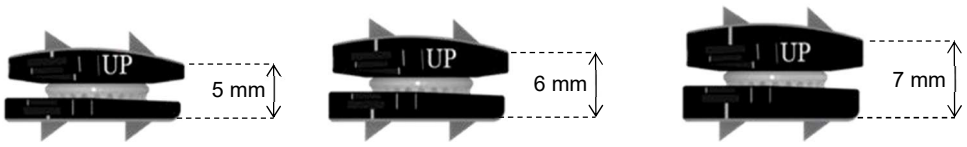

Figure V-3 BAGUERA® C Cervical Disc Prosthesis height range, where height corresponds to the posterior height of the prosthesis.

Table 1 The BAGUERA® C Cervical Disc Prosthesis Product Range

Height	SMALL: 13x16mm	MEDIUM: 14x17mm	LARGE: 16x18mm
5 mm	BAG-CT 13 05-S	BAG-CT 14 05-S	BAG-CT 16 05-S
6 mm	BAG-CT 13 06-S	BAG-CT 14 06-S	BAG-CT 16 06-S
7 mm	BAG-CT 13 07-S	BAG-CT 14 07-S	BAG-CT 16 07-S

VI. ALTERNATIVE PRACTICES AND PROCEDURES

There are several other alternatives for the treatment of intractable radiculopathy (arm pain and/or a neurological deficit) with or without neck pain, or myelopathy due to a single-level or two-contiguous-level abnormality localized to the level(s) of the disc space. These alternative treatments are summarized below:

- Nonoperative alternative treatments, which include, but are not limited to, simple neck adjustments, physical therapy, traction, heat, medications, braces, chiropractic care, bed rest, 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 using intervertebral cages, with various bone grafting techniques, with or without supplemental anterior plating
    - Decompression with posterior spinal systems (e.g., rods, hooks, wires)
    - Another FDA-approved artificial cervical disc

Each option has its own advantages and disadvantages. A patient should fully discuss these alternatives with his/her physician to select the method that best meets expectations and lifestyle.

VII. MARKETING HISTORY

The BAGUERA® C Cervical Disc Prosthesis has been marketed outside of the United States since 2007. It is currently distributed in Spain, Germany, France, Belgium, Portugal, United Kingdom, Ireland, Italy, Austria, Switzerland, Greece, Monaco, Poland, Romania, Slovakia, Russian Federation, China, Korea, Taiwan, Australia, New Zealand, Malaysia, Singapore, Thailand, Vietnam, Mauritius, Mexico, Cayman Islands, Dominican Republic, Panama, Peru, Martinique, Argentina, Brazil, Colombia, Uruguay, Venezuela, Algeria, South Africa, Iraq, Israel, India, Kazakhstan, Kuwait, Saudi Arabia, United Arab Emirates. The BAGUERA® C Cervical Disc Prosthesis has 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 BAGUERA® C Cervical Disc Prosthesis clinical study results, approved device labeling for other cervical total disc replacement devices, and published scientific literature including: (1) those associated with any general surgical procedure; (2) those associated with anterior cervical spine surgery; and (3) those associated with a cervical artificial disc device, including the BAGUERA® C Cervical Disc Prosthesis. 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.

General Surgery Risks

General surgical risks include but are not limited to: infection/abscess/cyst, localized or systemic, 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), and death.

Anterior Cervical Surgery Risks

Anterior cervical surgical risks include, but are not 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, and death.

Cervical Artificial Disc Risks

Risks specific to cervical artificial discs, including the BAGUERA® C Cervical Disc Prosthesis, 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, 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, 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, and death.

These conditions do not include all potential adverse events (AEs) that may occur but are important considerations in relation to the use of the BAGUERA® C Cervical Disc Prosthesis. For specific AEs that occurred in the single-level and two-contiguous level clinical studies, please see Section X.A.4 and Section X.B.4 respectively.

IX. SUMMARY OF PRECLINICAL STUDIES

A variety of testing was conducted to characterize the performance of the BAGUERA® C Cervical Disc Prosthesis, including:

Laboratory Studies

- Static Axial Compression
- Dynamic Axial Compression
- Static Compression Shear
- Dynamic Compression Shear
- Subluxation/ Expulsion
- Subsidence
- Wear (Mode I Wear)
- Third Body Wear (Mode 3 Wear)
- Impingement (Mode 4 Wear)
- Coating Testing

Additional Studies

- MR Compatibility
- Biocompatibility/ Pyrogenicity/ Neurotoxicity
- Device Sterilization
- Shelf Life and Transit Validation

A. Laboratory Studies

A summary of the conducted laboratory testing is presented in the following table, stratified by the above classifications (Table 2).

Table 2 Non-Clinical Study Summary

Test Name	Purpose	Test Method	Acceptance Criteria	Results
Static and Dynamic Strength				
Static Axial Compression	Verify the performance of the BAGUERA® C under simulated physiologic conditions is sufficient to withstand *in vivo* static compressive loads.	Five (5) final, finished, sterilized BAGUERA® C devices were aged per ASTM F2003 and tested under static compression at a rate of 25 mm/min until functional failure occurred or a specified load limit of 10 kN was reached. Testing was according to ASTM F2346.	The yield load must be at least 74 N[1].	Average yield load: 2180.0 N Static stiffness (for information only): 2,886.8 N/mm. The acceptance criteria were met.
Dynamic Axial Compression	Verify the performance of the BAGUERA® C under simulated physiologic conditions is sufficient to withstand *in vivo* dynamic (fatigue) compressive loads.	Three (3) final, finished, sterilized BAGUERA® C devices were aged per ASTM F2003 and tested under dynamic compression in 0.9% saline solution to 10 million cycles using a 2 Hz sinusoidal wave form with R=10. Testing was according to ASTM F2346.	The runout load must exceed 74[1] N at 10 million cycles.	Three samples were tested to 10 million cycles at 500 N of axial compression. No mechanical or functional failures were observed. The acceptance criteria were met.
Static Compression – Shear	Verify the performance of the BAGUERA® C under simulated physiologic conditions is sufficient to withstand *in vivo* static compression - shear loading.	Five (5) final, finished, sterilized BAGUERA® C devices were aged per ASTM F2003 and tested under a static axial load with samples positioned at 45° relative to the loading axis at a rate of 25 mm/min , until functional failure occurred or a specified load limit of 10 kN was reached. Testing was according to ASTM F2346.	The yield load must be at least 20 N[1].	Average yield: 1342.8 ± 64.4 N. The acceptance criteria were met.
Dynamic Compression – Shear	Verify the performance of the BAGUERA® C under simulated physiologic conditions is sufficient to withstand *in vivo* dynamic compression - shear loading.	Three (3) final, finished, sterilized BAGUERA® C devices were aged per ASTM F2003 and tested under dynamic compression in 0.9% saline solution to 10 million cycles using a 2 Hz sinusoidal wave form with R=10. Testing was according to ASTM F2346.	The runout load must exceed 20 N[1] at 10 million cycles.	Three samples were tested to 10 million cycles at 300 N of compression shear. No mechanical or functional failures were observed. The acceptance criteria were met.

Test Name	Purpose	Test Method	Acceptance Criteria	Results
Subluxation / Expulsion				
Subluxation and Expulsion	Verify the ability of the BAGUERA® C to resist expulsion and subluxation using simulated physiologic conditions.	Ten (10) final, finished, sterilized BAGUERA® C devices were aged per ASTM F2003 and provided for testing: n=5 for subluxation and n=5 for expulsion. Devices were tested at a rate of 6 mm/min in the posterior to anterior direction for a minimum of 3mm of total device displacement under a constant axial load of 150 N. Horizontal load and displacement was collected at a sampling rate of 100 Hz.	The subluxation and expulsion force must be at least 20 N[1].	The average subluxation force was 241 ± 13 N, which meets the acceptance criteria. There was also no evidence of mechanical or functional failure of the devices. The average expulsion force was 298 ± 4 N which meets the acceptance criteria. There was also no evidence of mechanical or functional failure of the devices.
Subsidence				
Subsidence	Verify the ability of the BAGUERA® C to resist subsidence using simulated physiologic conditions.	Five (5) final, finished, sterilized BAGUERA® C devices were aged per ASTM F2003. The devices were axially loaded at a rate of 0.1 mm/s until contact occurred between the superior and inferior foam test blocks. Load, displacement, and signs of mechanical damage to the implant and test blocks were recorded. Testing was conducted per ASTM F2267.	The yield load offset displacement at 1mm must be greater than 74 N[1].	The yield load was 1222 ± 95 N and yield displacement was 2.6 mm, and the K_p was 1078 ±119 N/mm, which meets the acceptance criteria.
Creep and Relaxation				

Test Name	Purpose	Test Method	Acceptance Criteria	Results
Creep and Stress Relaxation	To evaluate the creep characteristics of the BAGUERA® C .	Six (6) final, finished, sterilized BAGUERA® C devices were aged per ASTM F2003 and tested to evaluate the extent of creep under a constant load for a duration of over 1000 hours. Testing was in accordance with ASTM D2990-17. Each device was loaded on a custom fixture and subjected to a constant 150 N load, initially applied at 30 N/s. Displacement was recorded for 1, 6, 12, and 30 minutes and at 1, 2, 5, 20, 50, 100, 200, 500, 700, and 1000 hours.	No devices should demonstrate evidence of mechanical or functional failure, and the nucleus of the finished device shall not lose more than 0.20 mm of height after 1,000 hours of testing.	The average displacement under a constant load of 150 N after 1000 hours was 0.11 ± 0.05 mm. No evidence of mechanical or functional failure of the devices was observed. The devices met the acceptance criteria.
Wear				
Wear, Mode I (Pristine Wear Testing)	Characterize *in vivo* wear properties.	Ten (10) test articles were tested. Four (4) were for load soak and soak controls and six (6) for wear testing. All samples were subjected to 6 weeks of accelerated aging per ASTM F2003 prior to testing. Six (6) devices were subjected to 10 x 10^6 cycles of loads and motions prescribed for cervical disc prostheses in ASTM 2423 and ISO 18192-1 while submerged in bovine serum solution with a protein concentration of 5g/L. The test profiles used in the testing were: ±7.5° flexion-extension, ±6° lateral bending, ±6° rotation, and 50 – 150 N compressive axial load. A motion profile with a constant frequency of 1.0 Hz was applied to each specimen.	The device will reach 10 MC without mechanical or functional failure.	Average total mass loss: 6.0 ± 1.3 mg Average mass loss rate: 0.6 ± 0.1 mg/MC No devices demonstrated signs of mechanical or functional failure. All acceptance criteria were met.

Test Name	Purpose	Test Method	Acceptance Criteria	Results
Wear, Mode III (Abrasion)	To characterize in vitro wear properties under third-body abrasive wear conditions	Testing based on ISO 18192-1 and ASTM F2423. Specimens were subjected to combined ±7.5° flexion/extension, ±6°axial rotation, and ±6° lateral bending while submerged in third-body titanium particle slurry bovine serum lubricant. Testing was performed at 1.0 Hz with a 50-150 N applied load.	N/A, for characterization purposes	Mean mass wear rates – - Superior Endplate: 0.3 mg/MC at 1MC, 0.1 mg/MC at 5MC - AO-XLPE Core: 2.8 mg/MC at 1MC, 1.6 mg/MC at 5MC - Inferior Endplate: 0.2 mg/MC at 1MC, 0.1 mg/MC at 5MC. Average scratch height of 1.7µm in the superior endplates and 0.6µm on the inferior endplates. Average penetration of 0.25 ± 0.1 mm for the wear stations and had a penetration measurement range of 0.0 mm to 0.1 mm for the load soak stations after 5.0 MC. No measurable penetration on the articulating surfaces of the superior and inferior endplates following 5.0 MC of testing. Particle analysis shows size distributions and morphology in ranges consistent with other spine/ortho devices. No devices demonstrated signs of fracture or functional failure.

Test Name	Purpose	Test Method	Acceptance Criteria	Results
Wear, Mode IV (Impingement)	Characterize the impingement properties using simulated physiologic conditions.	Ten (10) test articles were tested. Four (4) were for load soak and soak controls and six (6) for wear testing. All samples were subjected to 6 weeks of accelerated aging per ASTM F2003 prior to testing. Six (6) devices were then subjected to 1 x 10^6 cycles in a posterior impingement position of combined 150 N axial load, 12-20° flexion and extension and ±4° axial rotation at 1 Hz per ISO 18192-1 and ASTM F3295 while submerged in bovine serum solution with a protein concentration of 5 g/L.	The device will reach 1 MC without mechanical or functional failure.	Average total mass loss: SM: 13.6 mg LG: 7.7 mg Average mass wear rates: SM: 13.2 mg/MC LG: 6 mg/MC No devices demonstrated signs of mechanical or functional failure.
Porous Titanium Coating Testing				
Coating Shear Fatigue	Evaluate coating in shear fatigue testing.	Fifteen (15) test specimens were tested per ASTM F1160.	No defect after 10^7 cycles at 10MPa.	None of the test specimens showed any evidence of coating failure. The acceptance criterion was met.
Coating Static Shear Strength	Evaluate coating in static shear testing.	Thirty (30) test samples were tested per ASTM F1044.	> 20 MPa	Range (min-max) 52.5- 74.6MPa The acceptance criterion was met.
Coating Static Tensile Strength	Evaluate coating in tensile testing.	Thirty (30) test samples were tested per ASTM F1147.	> 22 MPa	Range (min-max): 35.6-72.3MPa The acceptance criterion was met.
Coating Abrasion	Coating taber abrasion testing.	Fifteen (15) test specimens were tested per ASTM F1978.	< 65 mg after 100 cycles.	Average mass loss after 100 cycles was less than 65 mg after 100 cycles. The acceptance criterion was met.
Coating Characterization	Characterize coating morphology.	Visual inspection, n = 90.	Homogeneity	Homogeneous coating present. The acceptance criterion was met.

Test Name	Purpose	Test Method	Acceptance Criteria	Results
		Coating thickness per ASTM 1854, n = 90.	150 ± 30 µm (120-180µm)	Range (min-max): 132.3-172.9 µm The acceptance criterion was met.
		Coating porosity per ASTM 1854, n = 90.	30 ± 10% (20-40%)	Range (min-max): 22.7- 36.1% The acceptance criterion was met.
		Coating roughness (Rt) based on ISO 21920, n = 90.	156 – 354 µm	Range (min-max): 237.3- 327.0 µm The acceptance criterion was met.
DLC Coating Testing				
Coating Shear Fatigue	Evaluate coating in shear fatigue testing.	Fifteen (15) test specimens were tested per ASTM F1160.	No defect after 10^7 cycles at 10MPa.	None of the test specimens showed any evidence of coating failure. The acceptance criterion was met.
Coating Static Shear Strength	Evaluate coating in static shear testing.	Thirty (30) test samples were tested per ASTM F1044.	> 20 MPa	Range (min-max): 39.8-54.7MPa The acceptance criterion was met.
Coating Static Tensile Strength	Evaluate coating in tensile testing.	Thirty (30) test samples were tested per ASTM F1147.	> 22 MPa	Range (min-max): 40.2-65.4MPa The acceptance criterion was met.
DLC Coating Characterization	Characterize coating morphology.	Visual inspection, n = 102	Homogeneous coating[2]	Homogeneous. Acceptance criterion was met.
		Coating thickness per ASTM 1854 (n=102)	2 – 3 µm	Range (min-max): 2.0-2.5µm
		Coating adhesion, n = 102 (PQ) per ISO 26443	Class 0 – Class 1 (Load: 100kg)	All samples met the acceptance criterion.
		Coating roughness (Ra), n = 102 (PQ) per ISO 21920	≤ 0.1 µm	All samples met the acceptance criterion.

Test Name	Purpose	Test Method	Acceptance Criteria	Results
Nucleus Material Comparative Assessment				
Material Characterization	Characterize two (UHMWPE and AO-XLPE) polyethylene materials.	UHMWPE and AO-XLPE nucleus materials were subjected to all non-clinical laboratory testing. Additionally, AO-XLPE nuclei were included in the wear particle generation for the rabbit particulate study.	Minimal to no impact on BAGUERA® C: • Surgical technique • Design, range, and kinematics • Cleaning, packaging, sterilization • Biocompatibility • Manufacturing • Clinical safety / performance	The AO-XLPE material demonstrated minimal to no impact on the BAGUERA® C .

1. White AA, Panjabi MM. Clinical Biomechanics of the Spine. 2nd ed., J.B. Lippincott Company, 1990.
2. Under magnification x2.3, no shock, lack of coating, adhesion defect, electric arc, coloration > 300 µm and no more than 3 defects < 300µm in the functional area of the parts.

B. Animal Studies - Rabbit

A particulate injection study was conducted in rabbit models to evaluate potential toxicity associated with debris and particulate obtained from AO-XLPE, Ti6Al4V and DLC particulates when placed in direct contact with the spinal column via epidural injection. Summary data for this study is provided in the following table.

Table 3 Animal Study Summary

Test Name	Purpose	Test Method	Acceptance Criteria	Results
Injection Study	To evaluate the local effects of AO-XLPE, Ti6Al4V and DLC wear debris	Rabbits were injected in the epidural space (i.e. target placement on nerve root and in proximity to dura) with a negative control (NC) solution (sterile saline), a control (SPC) solution (AO-XLPE particulate) or a test solution (effective dose of ~4 mg of the dried wear debris particulates suspended in ~400 µL of sterile saline providing an approximate dose of 1.1 mg/kg injected into n=54 total rabbits) representative of wear debris. Rabbits were terminated at 4, 13 and 26 weeks. Local and distant tissues were harvested and examined for gross pathology (if present) and the tissue was analyzed histologically.	The test was for characterization purposes and acceptance criteria were not established.	Characterization of response to wear particles near the spine. There were no adverse clinical or macroscopic observations that are related to test, SPC, or NC article applications in 4--, 13-, and 26-week animals. There was no macroscopic or microscopic evidence of systemic toxicity in the liver and spleen tissues following intra-epidural injection of the TA, or the SPC at 4-, 13- or 26-weeks post-injection. A small amount of intracytoplasmic black

Test Name	Purpose	Test Method	Acceptance Criteria	Results
				pigment present within macrophages (interpreted to be the DLC coating) were found in the epidural space of almost all test animals at all three time points. The TA elicited minimal or no reaction when compared to the SPC and NC articles.

C. Additional Studies

a) Magnetic Resonance (MR) Imaging

The safety and compatibility of the BAGUERA® C Cervical Disc Prosthesis in the Magnetic Resonance (MR) environment was evaluated. Specifically, it was tested for magnetic field interactions, heating, and artifacts associated with clinically relevant magnetic resonance imaging.

The magnetic field interaction evaluations consisted of displacement and torque assessments. For the assessment of displacement, an induced displacement force test was performed in accordance with ASTM F2052. The evaluation of magnetic torque was performed in accordance with ASTM F2213. The BAGUERA® C Cervical Disc Prosthesis was tested for MRI-related heating in accordance with ASTM F2182. MR imaging artifacts were assessed in accordance with ASTM F2119.

The results of the assessments demonstrated that the BAGUERA® C Cervical Disc Prosthesis is MR Conditional. A patient with the BAGUERA® C Cervical Disc Prosthesis can be scanned safely in an MR system under the following conditions:

- Static magnetic field of 1.5 Tesla (1.5T) or 3.0 Tesla (3.0T).
- Maximum spatial gradient field less than or equal to 4,000 Gauss/cm (40 T/m).
- Operating mode, allowable whole-body SAR (SAR_{wb}), and/or allowable B_{1+RMS} varies by landmark position as detailed below:
    - 1.5 T: Normal Operating Mode
    - 3 T: Normal Operating Mode from navel to bottom of foot; $SAR_{WB} \leq 0.4$ W/kg or $B_{1+RMS} \leq 2$ μT from bottom of mandible to navel.

- Scan Duration: under the exposure conditions outlined in Operating Mode section above, up to 1 hour of continuous scanning is permissible without a cooling period.
- Scan Region: under the exposure conditions outlined in Operating Mode section above, any landmark is acceptable.

In non-clinical testing per ASTM F2119, the image artifact caused by the BAGUERA® C Cervical Disc Prosthesis extends approximately 2.6 cm for a Gradient Echo scan at 3T. Some manipulation of scan parameters may be needed to compensate for the artifact.

b) Biocompatibility

The BAGUERA® C Cervical Disc Prosthesis is manufactured from Titanium alloy, diamond-like carbon, vitamin E blended crosslinked high-density polyethylene, and commercially pure titanium plasma spray (TPS). All implant materials have a long history of successful orthopedic and cardiovascular clinical use and well-established biocompatibility.

Biocompatibility testing was performed on the BAGUERA® C Cervical Disc Prosthesis in its final sterilized state in accordance with ISO 10993-1, ISO 10993-12, ISO 10993-17, and ISO 10993-18, for the level of contact duration of a permanent implant contacting tissue and bone. The battery of biocompatibility tests conducted included: Cytotoxicity (ISO 10993-5), Pyrogenicity (ISO 10993-11), Bacterial Endotoxin Evaluation (ANSI/AAMI ST72, USP<85>, USP<161>), and Biological Risk Assessment (ISO 10993-1, -12, -17, -18). All test results met the acceptance criteria demonstrating biocompatibility in line with the requirements of ISO 10993-1.

c) Sterilization Validation

Full sterilization validation has been conducted for the BAGUERA® C Cervical Artificial Disc implants per ISO 11137. Full sterilization validation has been conducted for the BAGUERA® C Cervical Artificial Disc Instruments per ANSI/AAMI ST79, AAMI TIR12, and ISO 17665-1.

d) Shelf Life and Transit Validation

Shelf life and transit validation studies, including assessments of packaging seal integrity and real-time aging stability testing, were conducted to demonstrate that the device packaging can maintain a sterile barrier over an 8-year shelf life.

X. SUMMARY OF PRIMARY CLINICAL STUDIES

The applicant performed two clinical studies to establish a reasonable assurance of safety and effectiveness of replacement of the degenerated disc with the BAGUERA® C Cervical Disc Prosthesis following single-level and two-contiguous level discectomy for intractable radiculopathy (arm pain and/or a neurological deficit) with or without neck pain, or myelopathy due to a single-level or two-contiguous level abnormality localized to the level(s) of the disc space and manifested by at least one of the following conditions confirmed by radiographic imaging (e.g., X-rays, computed tomography (CT), magnetic resonance imaging (MRI)): herniated nucleus pulposus, spondylosis (defined by the presence of osteophytes), and/or visible loss of disc height as compared to adjacent levels. The studies were performed in the United States under IDE G200182 (single-level) and IDE G200239 (two-contiguous levels). The IDE studies consisted of one-level and two-level treatment populations each enrolled in two separate concurrent clinical studies. A summary of the one-level clinical study is provided below in section A, a summary of the two-level clinical study is provided below in section B. Data from these clinical studies were the basis for the PMA approval decision.

Summaries of the clinical studies are presented below.

A. Single-Level Cervical Disc Replacement

1. Pivotal Study Design

Subjects in the pivotal clinical trial were treated between February 2021 and March 2024. The prospective, multi-center, randomized, controlled clinical study was conducted under IDE G200182 to compare the BAGUERA® C Cervical Disc Prosthesis (investigational device) to the Mobi-C® Cervical Disc (control device), a PMA approved artificial cervical disc.

The database for this PMA reflects data collected on a total of 309 subjects that signed the informed consent and were randomized in the study. Of the 309 subjects, 24 of these subjects remained blinded, and ultimately were not treated, while 285 of these subjects (N=189 BAGUERA® C; and N=96 Mobi-C) had an incision time recorded and were enrolled in the study. Subjects were treated at 25 US sites. Subjects were randomized in a 2:1 ratio to the single level BAGUERA® C device (investigational group) or to the single-level Mobi-C device (control group), respectively. A statistical plan was designed to test non-inferiority between the two groups.

a) 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 4:

Table 4 Study Inclusion and Exclusion Criteria for IDE G200182 (single-level)

Study Inclusion Criteria	Study Exclusion Criteria
In order to be eligible to participate in this study, subjects must meet all of the following criteria: 1. Male or female; skeletally mature; age 22-69 years, inclusive. 2. Diagnosis of radiculopathy or myeloradiculopathy of the cervical spine, with pain, paresthesia or paralysis in a specific nerve root distribution C3 through C7, including at least one of the following: a. Neck and/or arm pain (at least 40 mm on the 100 mm visual analogue scale [VAS] scale). b. Decreased muscle strength of at least one level on the clinical evaluation 0 to 5 scale. c. Abnormal sensation including hyperesthesia or hypoesthesia; and/or d. Abnormal reflexes. 3. Symptomatic cervical disc disease (SCDD) at one level from C3 to C7.	Subjects who meet any of the following criteria will be excluded from participating in this study: 1. Have an active systemic infection or infection at the operative site. 2. Have a history of or anticipated treatment for active systemic infection, including HIV or Hepatitis C. 3. More than one immobile vertebral level between C1 to C7 from any cause including but not limited to congenital abnormalities and osteoarthritic "spontaneous" fusions. 4. Previous trauma to the C3 to C7 levels resulting in significant bony or disco-ligamentous cervical spine injury. 5. Had any prior spine surgery at the operative level. 6. Had a prior cervical fusion or artificial disc procedure at any cervical level.

Study Inclusion Criteria	Study Exclusion Criteria
4. Radiographically determined pathology at the level to be treated correlating to primary symptoms including at least one of the following: a. Decreased disc height on radiography, computed tomography (CT), or magnetic resonance imaging (MRI) in comparison to a normal adjacent disc. b. Degenerative spondylosis on CT or MRI. c. Disc herniation on CT or MRI. 5. NDI Score of ≥ 30% (raw score of ≥15/50). 6. Preoperative neck or arm pain ≥ 40 (out of 100) on Preoperative Neck and Arm Pain Questionnaire. 7. Unresponsive to non-operative, conservative treatment (including but not necessarily limited to: rest, heat, electrotherapy, physical therapy, chiropractic care and/or analgesics) for: a. Approximately six weeks from radiculopathy or myeloradiculopathy symptom onset; or b. Have the presence of progressive symptoms or signs of nerve root/spinal cord compression despite continued non-operative conservative treatment. 8. Appropriate for treatment using an anterior surgical approach, including having no prior surgery at the operative level and no prior cervical fusion or cervical artificial disc procedure at any level. 9. Medically cleared for surgery. 10. 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. 11. Written informed consent provided by subject	7. Axial neck pain in the absence of other symptoms of radiculopathy or myeloradiculopathy. 8. Disc height less than 3 mm as measured from the center of the disc in a neutral position. 9. Radiographic confirmation of severe facet joint degeneration or confirmed clinical evidence that facet joint degeneration is a major contributor to the subject's pain. 10. Have osteoporosis or osteopenia, defined as a DEXA bone density measured T-score of ≤ -1.5 (i.e. -1.6, -1.7, etc.). A DEXA performed within 24 months of the surgery date may be used to determine eligibility. For subjects without a DEXA within 24 months of the surgery date a score of ≥ 6 on either the SCORE or MORES requires a DEXA to determine eligibility. Note: *The SCORE (Simple Calculated Osteoporosis Risk Estimation) form should be administered if the subject is female. The MORES (Male Osteoporosis Risk Estimation Score) form should be administered if the subject is male.* 11. Have Paget's disease, osteomalacia or any other metabolic bone disease other than osteoporosis, which is addressed above. 12. Severe diabetes mellitus requiring daily insulin management. 13. Have an active malignancy that includes a history of any invasive malignancy (except non-melanoma skin cancer), unless the subject was treated with curative intent and there had been no clinical signs or symptoms of the malignancy for at least five years. 14. Symptomatic SCDD or significant cervical spondylosis at more than one level. 15. Spondylolysis. 16. Marked cervical instability on resting lateral or flexion-extension radiographs demonstrated by: a. Translation ≥ 3.5 mm, and/or b. Greater than 11° angular difference to that of either adjacent level. 17. Known allergy to Titanium, Vanadium, Aluminum, Cobalt, Chromium, Molybdenum or Polyethylene.

Study Inclusion Criteria	Study Exclusion Criteria
	18. Segmental angulation of greater than 11° at treatment or adjacent levels. 19. Pregnant at time of enrollment, or with plans to become pregnant within the next three years. 20. Have rheumatoid arthritis, lupus, or other autoimmune disease that affect the musculoskeletal system. 21. Congenital bony and/or spinal cord abnormalities that affect spinal stability. 22. Have diseases or conditions that would preclude accurate clinical evaluation (e.g. neuromuscular disorders, confirmed fibromyalgia, etc.). 23. Concomitant conditions requiring daily, high-dose oral and/or inhaled steroids. High dose steroid use is defined as: a. Daily, chronic use of oral steroids of 5 mg/day or greater. b. Daily, chronic use of inhaled corticosteroids (at least twice per day). c. Use of short-term (less than 10 days) oral steroids at a daily dose greater than 40mg within one month of the study procedure. 24. Have current or recent history of substance abuse (alcoholism and/or narcotic addiction) requiring intervention. 25. Severe Obesity, as defined by National Institutes of Health (NIH) Clinical Guidelines Body Mass Index (BMI) > 40). 26. Use of any investigational drug or other investigational medical device within the last 30 days prior to surgery. 27. 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 #23. 28. Currently pursuing litigation (defined as litigation that will likely influence the patient's ability or willingness to accurately report their treatment outcomes) related to the neck or cervical spine injury. 29. Current history of heavy nicotine use (e.g. more than one pack of cigarettes per day).

Study Inclusion Criteria	Study Exclusion Criteria
	30. Circumstances that may interfere with completion of follow-up examinations, including location of residence. 31. Belong to a vulnerable population (e.g., prisoner, ward of the court or developmentally disabled). 32. Currently experiencing an acute or chronic episode of confirmed specific mental illness (psychosis, major affective disorder, or schizophrenia), or manifesting physical symptoms without a diagnosable medical condition to account for the symptoms, which may indicate symptoms of psychological rather than physical origin. 33. Have an uncontrolled seizure disorder. 34. Received cervical spine epidural steroids within 14 days prior to surgery.

b) Control

Control subjects were prospectively enrolled and randomized to treatment with the Mobi-C® Cervical Disc (N=96), a PMA-approved artificial cervical disc. The Mobi-C Cervical Disc was implanted according to its surgical technique guide.

c) 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 6 weeks (±2 weeks), 3 months (±2 weeks), 6 months (±1 month), 1 year (±2 months), 2 years (±2 months), and annually thereafter (±2 months). The following parameters (Table 5) were measured throughout the study:

Table 5 BAGUERA® C Cervical Disc Prosthesis IDE G200182 Study Assessment Schedule

Procedures	Pre-op	Surgery	6 Weeks	3 Months	6 Months	12 Months	24 Months	Annual to 84 Months	Unscheduled
			± 2 wks	± 2 wks	± 4 wks	± 8 wks	± 8 wks	± 8 wks	
Informed consent	X	-	-	-	-	-	-	-	-
Demographics	X	-	-	-	-	-	-	-	-
Medical History	X	-	X	X	X	X	X	X	X
Work Status	X	-	X	X	X	X	X	X	-
Incl/Excl criteria	X	-	-	-	-	-	-	-	-
Randomization	X	-	-	-	-	-	-	-	-
Pregnancy Assessment	-	X	-	-	-	-	-	-	-
MRI or CAT scan	X	-	-	-	-	-	-	-	-
DEXA scan	X	-	-	-	-	-	-	-	-
AP Lat X-rays	X	X	X	X	X	X	X	X	-
Flex-Ext X-rays	X	-	X	X	X	X	X	X	-
Presenting Symptoms	X	-	X	X	X	X	X	X	-
Neuro Exam	X	X	X	X	X	X	X	X	X
Nurick Classification	X	-	-	-	-	-	-	-	-
Odom's Classification	-	-	-	-	-	-	X	X	-
NDI	X	-	X	X	X	X	X	X	X
Neck VAS	X	-	X	X	X	X	X	X	X
Left/Right Arm VAS	X	-	X	X	X	X	X	X	X
SF-12v2	X	-	-	-	X	X	X	X	-
Patient Satisfaction	-	-	X	X	X	X	X	X	-
Dysphagia Index	X	-	X	X	X	X	X	X	-
Medications	X	X	X	X	X	X	X	X	X
Adverse Events	-	X	X	X	X	X	X	X	X

d) Clinical Endpoints

The safety of the BAGUERA® C Cervical Disc Prosthesis 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, seriousness and relationship to the implant and/or surgical procedure), subsequent index level surgical procedures and maintenance or improvement in neurological status.

The effectiveness of the BAGUERA® C Cervical Disc Prosthesis was assessed using a composite endpoint, as described below. Effectiveness was evaluated by assessing improvement in the Neck Disability Index (NDI), neck and arm

pain Visual Analogue Scale (VAS) questionnaires, the Dysphagia Handicap Index (DHI), Odom's Criteria, health-related quality of life using the short-form questionnaire (SF-12v2), and patient satisfaction of the BAGUERA® C Cervical Disc Prosthesis treatment compared to the Mobi-C® Cervical Disc treatment. The same criteria were used to measure success in both groups.

Primary Endpoint

The study hypothesis for the BAGUERA® C Cervical Disc Prosthesis IDE G200182 Study was that the Month 24 (i.e., 24 months post-operatively) composite clinical success (CCS) rate of the single-level BAGUERA® C Cervical Disc Prosthesis would be no worse than conventional single-level MOBI-C® Cervical Disc when success is evaluated at Month 24 in patients with intractable radiculopathy (arm pain and/or a neurological deficit) with neck pain or myelopathy due to abnormalities localized at a single level from C3 to C7 that is unresponsive to conservative management or have presence of progressive signs or symptoms of nerve root/spinal cord compression.

Individual CCS for both the investigational and control groups was defined as:

1. Improvement in pain and function, as measured through the Neck Disability Index (NDI), of at least 15 percentage points (out of 100%) from pre-operative;
2. Maintenance or improvement in neurological status at 24 months compared to baseline (as determined by the CEC)
3. No secondary surgical intervention defined as revision, removal, reoperation, or supplemental fixation at the index level
4. No serious adverse event(s) confirmed as device or procedure related (as determined by the CEC).

Subjects who required device removal (explantation) were withdrawn from the study and were considered a treatment failure. In addition, subjects who required a secondary surgical intervention (SSI) at the index level were considered a treatment failure.

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: $\pi_T - \pi_C \leq -0.125$ (the CCS rate of investigational device was clinically inferior to control)

H_a: $\pi_T - \pi_C > -0.125$ (the CCS rate of investigational device was not clinically inferior to control)

where π_T and π_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, $\delta = 0.125$.

The claim of non-inferiority was pre-specified to be accepted if the posterior probability of non-inferiority, is greater than or equal to 0.95. That is, if, $Pr(\pi T - \pi C > -0.125 \mid \text{Trial Results}) \geq 0.95$.

This posterior probability is calculated using Beta(1, 1) non-informative priors for both the investigational and control arms. A Bayesian posterior probability threshold of 0.95 controls type 1 error to 0.05 and supplies statistical power in excess of 80%.

Per the 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 apply:

- Reoperation – Any surgical procedure at the index level that does not involve modification, addition or removal of any components of the device in the postoperative or follow-up period.
- Revision – Any procedure in the postoperative 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 postoperative or follow-up period.
- Removal – A procedure where the entire device is removed with or without replacement of the device in the postoperative or follow-up period.
- Supplemental fixation – A procedure in which additional instrumentation not under study is implanted (e.g. supplemental placement of a rod/screw system).

Secondary Endpoints

Secondary endpoints, measured in both treatment groups, included:

- Time to recovery (time to first 15 percentage points – out of 100 NDI – improvement)
- Left and right arm pain 100mm Visual Analogue Scale (VAS) (an improvement in pain of at least 20mm on the VAS is considered clinically significant)
- Neck pain 100mm Visual Analogue Scale (VAS) (an improvement in pain of at least 20mm on the VAS is considered clinically significant)

- Dysphagia Handicap Index (24 months compared to baseline)
- Health Related Quality of Life (SF-12v2) Physical Component Summary (PCS)
- Patient Satisfaction
- Odom's Criteria to measure surgical success (determined by the treating physician)

Other Clinical Measures:

Other clinical measures, evaluated in both treatment groups, included:

- Operative time
- Estimated blood loss
- Length of hospital stay
- Work status

Radiographic Assessments:

Radiographic assessments (performed by an independent imaging core lab), evaluated in both treatment groups, included:

- Quantitative Assessment included:
  - Angular Motion
  - Translational Motion
  - Anterior/Posterior/Average Disc Height and Change in Disc Height
  - Disc Angle and Change in Disc Angle
- Qualitative Assessment included:
  - Heterotopic Ossification (including bridging bone)
  - Device Condition
  - Device Migration
  - Device Subsidence
  - Superior Interface Radiolucency
  - Inferior Interface Radiolucency
  - Bone-Implant Interface Motion
  - Adjacent Level Disc Degeneration
  - Additional Radiographic Observations

e) Clinical Events Committee

A Clinical Events Committee (CEC) was utilized for the BAGUERA® C Cervical Artificial Disc IDE study to mitigate reporting bias of safety-related events. The CEC was comprised of three (3) independent spine surgeons, and a CEC charter was used to define the role of the CEC. The committee was responsible for adjudication of AE (i.e., relationship to device/procedure, seriousness, determination of unanticipated adverse device effects), secondary

surgical intervention (SSI) (i.e., classification of revision, removal, reoperation or supplemental fixation), protocol deviations (i.e., classification as Major or Minor), and neurological success criterion (classification of neurologic status at Month 24 as compared to baseline).

2. Accountability of PMA Cohort

At the time of the May 13, 2026 database lock, a total of 309 subjects signed the informed consent form and were randomized (Intent-to-Treat Analysis Set):

- A total of 24 subjects were randomized, remained blinded, and ultimately not treated.
  - 6 of the 24 subjects did not meet the eligibility criteria defined in Protocol prior to treatment.
  - 7 of the 24 subjects withdrew their consent to participate in the study.
  - 7 of the 24 subjects were withdrawn by the investigator prior to scheduling surgery
  - 4 of the 24 subjects were lost to contact by the study site and surgery could not be scheduled

The resulting 285 available randomized subjects, with an operation date at the time of the database lock (189 BAGUERA® C subjects and 96 Mobi-C control subjects) were assessed as part of the modified Intent-to-Treat (mITT) Analysis Set. All subjects treated received the treatment assigned by randomization; therefore, the As-Treated (AT) Analysis Set and Per Protocol (PP) Analysis Set are identical, 189 BAGUERA® C subjects, and 96 Mobi-C subjects. See Table 6 and Figure 4 below.

Table 6 Accounting Information – G200182 study (single-level)

	BAGUERA® C	**Mobi-C**
Randomized (Intention-To-Treat, ITT, population)	206	103
Subjects randomized but not treated	17	7
Modified Intention-to-Treat (mITT) Population	189	96
As Treated (AT) Population	189	96
Per Protocol (PP) Population	189	96
Subjects with known primary outcome (CCS) among mITT population	181	85
Subjects with missing CCS outcome among mITT population: - Not yet overdue (between day 730 and 790): - Missing for other reason: o Lost to Follow-up: o Death: o Missed 24 Month Visit	8 0 5 1 2	11 1 5 0 5

This submission includes data up to the database lock that occurred on May 13, 2026. The Month 24 CCS endpoint within the mITT/PP Analysis Set is based on 99.6% (284/285) of all subjects expected due. Within the mITT Analysis Set, 100% (189/189) of BAGUERA® C subjects, and 99% (95/96) of Mobi-C subjects are theoretically due (Day 730); within this same analysis set, 96% (181/189) of BAGUERA® C subjects, and 89% (85/96) of Mobi-C subjects have a known primary outcome.

The subject accountability summary through the Month 24 timepoint is presented in Table 7 for the mITT Analysis Set. The accounting table is stratified by treatment arm with the overall BAGUERA® C group subjects referred to hereafter as the investigational group ("I"), and Control group ("C") for subjects that have completed follow up through Month 24.

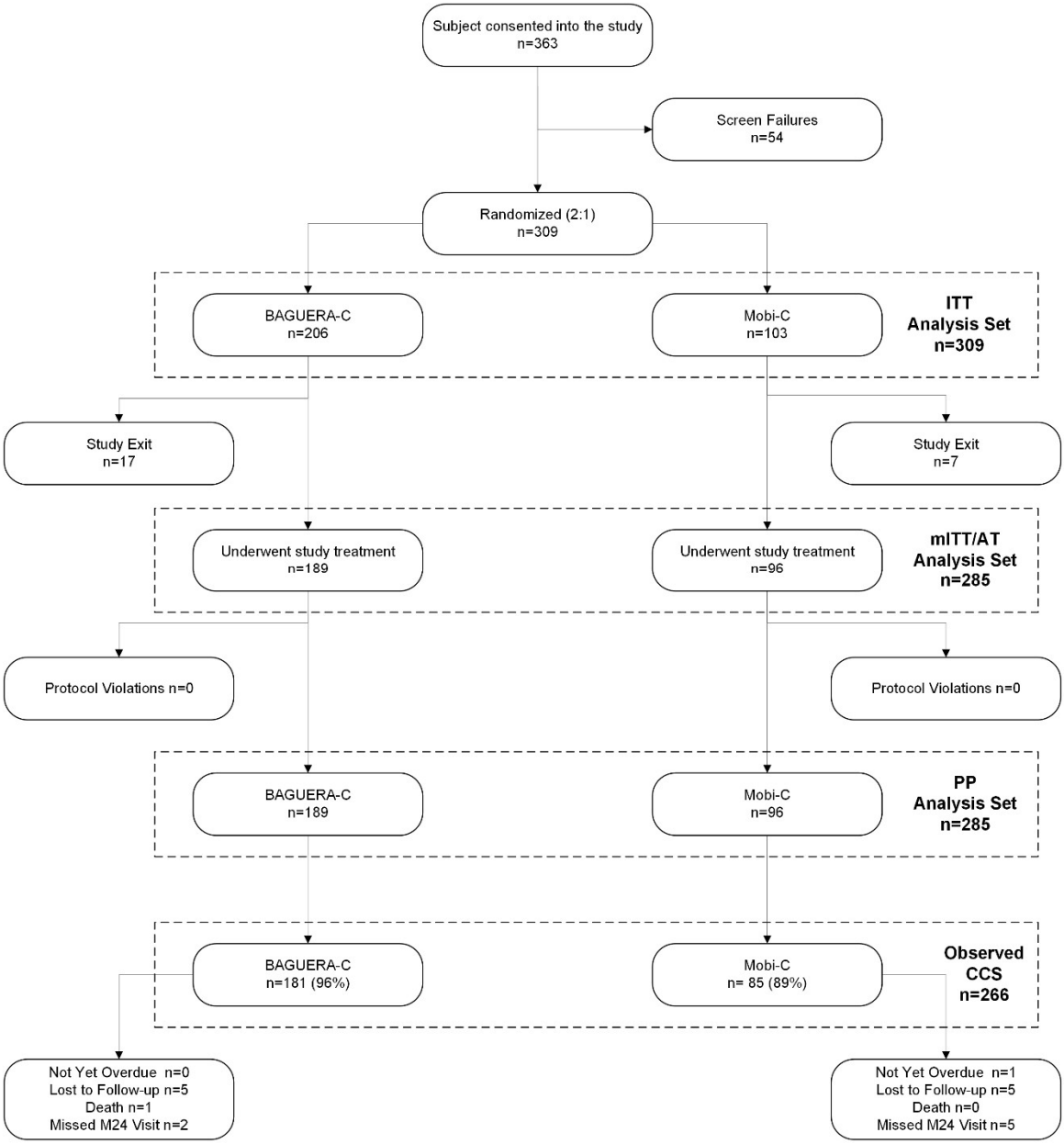

Figure 4 IDE G200182 (single-level) study. Subject Accountability Tree

Table 7 G200182 – Subject Accounting Summary Through Month 24 (Day 730). mITT Analysis Set

	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
Accounting														
(1) Theoretical follow-up	189	96	189	96	189	96	189	96	189	96	189	96	189	96
(2) Cumulative Death			0	0	0	0	0	0	0	0	1	0	1	0
(3) Cumulative SSI Failures			0	0	0	0	0	0	0	0	4	3	7	3
(4) Not Yet Overdue			0	0	0	0	0	0	0	0	0	0	0	1
(5) Deaths + SSI failures among theoretically due			0	0	0	0	0	0	0	0	5	3	8	3
(6) Expected Due [(6) =(1)-(4)-(5)]					189	96	189	96	189	96	184	93	181	92
(7) SSI failures among theoretically due			0	0	0	0	0	0	0	0	4	3	7	3
(8) Expected due + SSI failures among theoretically due [(8)=(6)+(7)]					189	96	189	96	189	96	188	96	188	95
All Evaluated Accounting (Actual[B]) Among Expected Due Procedures														
(9) Procedures with any clinical data in interval†	189	96			189	95	184	93	187	94	179	90	174	82
(10) Visit Compliance (%)					100%	99%	97%	97%	99%	98%	97%	97%	96%	89%
(11) Change in NDI							184	93	187	94	179	89	174	82
(12) Composite Clinical Success (CCS)													174	82
(13) Actual[B] % Follow-up for CCS													96%	89%
Within Window Accounting (Actual[A]) Among Expected Due Procedures														
(14) Procedures with any clinical data in interval†	189	96			128	67	160	81	135	62	174	85	160	77
(15) Visit Compliance (%)					68%	70%	85%	84%	71%	65%	95%	91%	88%	84%
(16) Change in NDI							160	81	135	62	174	84	160	77
(17) Composite Clinical Success (CCS)													160	77
(18) Actual[A] % Follow-up for CCS													88%	84%
Composite Clinical Success														
(19) Composite Clinical Success (CCS)													181	85
(20) Actual[A] % Follow-up for CCS													96%	89%

†NDI value at baseline, change in NDI at follow-up visits.
Source: Tables Follow-up Compliance 1L.sas; Analyzed: 19JUN2026

The following definitions apply to Table 7 above:

[1] **Theoretical follow-up**: The theoretical follow-up is the number of subjects treated that would have been examined if all subjects returned on the exact anniversary of their respective initial treatment dates. The theoretical follow-up is determined by selecting a date of database closure (i.e., the date the database was closed to the addition of information). The theoretical row is the treated subjects less those not yet due for a follow-up visit. The date of database closure for the analysis will be listed at the top of the table.

[2] **Cumulative Deaths**: Cumulative deaths up to the date of the exact anniversary defining the current interval. Deaths occurring after the exact anniversary are recorded in the next interval. Although the cumulative numbers of deaths are recorded on this row, only deaths among subjects that are theoretically due for that interval are subtracted from theoretically due to determine the number expected due for clinical index evaluation.

[3] **Cumulative Secondary Surgical Intervention (SSI) Failures**: Cumulative SSI failures up to the date of the exact anniversary defining the current interval. SSI failures occurring after the exact anniversary are recorded in the next interval. Although the cumulative numbers of SSI failures are recorded on this row, only additional events among subjects that are theoretically due for that interval are subtracted from theoretically due to determine the number expected due for clinical index evaluation.

[4] **Not Yet Overdue**: Includes subjects whose treatment anniversary has occurred; however, clinical data has not yet been collected (e.g., NDI is currently unavailable), but the patient is still in the protocol-specified follow-up window. Such subjects may yet be observed, and so follow-up compliance estimates account for this by removing such subjects from the denominator as well as from the numerator when determining compliance ratios.

[5] **Deaths + Cumulative Secondary Surgical Intervention Failures among theoretically due**: This row records the sum of deaths and Secondary Surgical Interventions among those theoretically due for follow-up according to the exact anniversary of the scheduled follow-up visit.

[6] **Expected due for clinic visit**: This row is the number of subjects expected for a given time interval. These include the theoretical number of subjects who are due to be evaluated, less the number of subjects who died, and less the number of subjects in the "Not yet overdue" category. Expected = Theoretical - [Deaths + SSI Failures+ Not yet overdue] where the counts of the numbers of deaths and Not Yet Overdue are determined from among the theoretically due subjects. This row serves as the denominator for evaluation % follow-up for clinical indices (e.g., NDI). The Expected row includes subjects lost to follow-up, and major protocol violations are included in the expected group for all time points.

[7] **SSI Failures among theoretically due:** This row records the Secondary Surgical Interventions among those theoretically due for follow-up according to the exact anniversary of the scheduled follow-up visit.

[8] **Expected due + SSI Failures among theoretical due:** Expected due plus theoretical due Failures is computed by adding expected due in row (6) to the number of cumulative Failures among theoretically due devices in row (7). This row serves as the denominator for composite clinical success (CCS) outcomes since CCS status is known for subjects with a Failure as defined in row (3).

[9] **Procedures with any clinical data in the interval**: The number of subjects with any clinical data for all evaluated subjects among expected due procedures. If any case report is recorded with a date, the subject will be considered to have contributed any data in the interval.

[10] **Visit Compliance among expected (%)**: The percentage of subjects compliant with the specified visit scheduled for all evaluated subjects among expected due procedures. This rate will not necessarily equal the primary observed endpoint data.

[11] **Change in NDI**: The number of subjects reporting a change in NDI for all evaluated subjects among expected due procedures. Subjects without baseline NDI can never contribute to this row.

[12] **Composite Clinical Success (CCS):** These rows indicate the number of subjects with enough data available for evaluation of clinical composite success for all evaluated subjects among expected due procedures (12)

[13] **Actual [B] follow-up for CCS(%)**: The number of subjects with Month 24 CCS data among all subjects enrolled in the study. This will be the primary measure of study compliance.

[14] **Procedures with any clinical data in the interval**: Repeats (9) restricted to evaluations performed within the interval.

[15] **Visit Compliance among expected (%)**: Repeats (10) restricted to evaluations performed within the interval.

[16] **Change in NDI**: Repeats (11) restricted to evaluations performed within the interval.

[17] **Composite Clinical Success (CCS):** These rows indicate the number of subjects with enough data available for evaluation of clinical composite success for all subjects that are within window among expected due procedures (21).

[18] **Actual [A] follow-up for CCS (%)**: Repeats (13) restricted to evaluations performed within the interval.

[19] **Composite Clinical Success:** The number of subjects with primary endpoint data (Month 24 CCS), including terminal failures from SSIs, amongst all subjects enrolled in the study. This is the primary analysis set.

[20] **Actual [A] Follow-up for CCS:** The proportion of subjects with primary endpoint data, including terminal failures from SSIs, amongst all subjects enrolled in the study.

3. 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 single-level indications in the US.

Table 8 Baseline Demographic Continuous Variables. (mITT Analysis Set, N=285)

	BAGUERA® C						Mobi-C						Group Difference*			
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	Δ	LB	UB	p
All																
Age (years)	189	44.7	8.6	44.0	22.0	67.0	96	46.4	9.2	45.0	29.0	69.0	-1.7	-3.9	0.5	0.057
BMI (kg/m^2)	189	28.3	5.1	27.4	17.1	39.1	96	29.0	5.3	28.4	18.8	39.8	-0.7	-1.9	0.6	0.178
Height (in)	189	68.0	3.9	69.0	56.0	77.0	96	68.3	3.7	69.0	59.0	77.0	-0.3	-1.2	0.7	0.372
Weight (lbs)	189	186.7	37.8	185.0	97.9	285.0	96	192.6	40.4	190.0	113.0	300.0	-6.0	-15.7	3.8	0.148
Female																
Age (years)	86	42.3	6.4	42.0	28.0	64.0	38	45.4	9.1	45.5	29.0	63.0	-3.1	-6.3	0.1	0.015
BMI (kg/m^2)	86	28.1	6.0	26.6	17.1	39.1	38	29.3	6.5	27.8	18.8	39.8	-1.3	-3.7	1.2	0.157
Height (in)	86	64.9	3.0	65.0	56.0	72.0	38	65.2	2.9	65.0	59.0	71.0	-0.3	-1.4	0.8	0.360
Weight (lbs)	86	167.7	35.3	162.5	97.9	247.0	38	177.7	44.0	172.5	113.0	266.4	-10.0	-25.9	5.9	0.191
Male																
Age (years)	103	46.6	9.7	46.0	22.0	67.0	58	47.1	9.3	45.0	32.0	69.0	-0.4	-3.4	2.6	0.499
BMI (kg/m^2)	103	28.5	4.2	27.8	19.4	38.4	58	28.7	4.3	28.5	20.1	39.6	-0.2	-1.6	1.2	0.293
Height (in)	103	70.6	2.5	70.0	64.0	77.0	58	70.3	2.7	70.0	65.0	77.0	0.3	-0.5	1.1	0.172
Weight (lbs)	103	202.5	32.3	195.0	116.6	285.0	58	202.4	34.8	196.5	124.2	300.0	0.1	-10.8	11.0	0.487
Clinical Scores																
NDI	189	57.4	15.9	56.0	30.0	96.0	96	54.9	13.9	55.0	30.0	88.0	2.6	-1.0	6.1	0.101
VAS Neck Pain	189	73.6	19.7	75.0	3.0	100.0	96	74.3	20.6	77.5	0.0	100.0	-0.7	-5.7	4.3	0.253
VAS Right Arm Pain	189	44.9	36.4	53.0	0.0	100.0	96	44.1	37.6	48.0	0.0	100.0	0.7	-8.4	9.9	0.419
VAS Left Arm Pain	189	51.9	36.1	66.0	0.0	100.0	96	52.4	34.5	61.0	0.0	100.0	-0.5	-9.1	8.1	0.471
DHI Score	188	6.6	10.9	2.0	0.0	64.0	96	5.5	10.5	2.0	0.0	54.0	1.1	-1.5	3.7	0.105
SF-12v2 PCS	189	34.7	7.0	34.8	13.8	51.8	96	34.8	6.7	34.8	18.6	53.6	-0.1	-1.8	1.6	0.488
SF-12v2 MCS	189	45.6	11.5	45.8	18.2	67.1	96	45.8	11.7	47.0	18.6	66.7	-0.2	-3.0	2.7	0.425

*Device group mean differences and 95% Confidence Intervals with Wilcoxon p-value
Source: Tables Baseline Demo.sas; Analyzed: 19JUN2026

Table 9 Summary of Baseline and Demographic Categorical Variables – mITT Analysis Set

	BAGUERA® C			Mobi-C			Group Difference		
	N	n	%	N	n	%	Dif	95% LB	95% UB
Sex									
Female	189	86	45.5%	96	38	39.6%	5.9%	-6.2%	18.0%
Male	189	103	54.5%	96	58	60.4%	-5.9%	-18.0%	6.2%
Race									
American Indian or Alaska Native	189	3	1.6%	96	1	1.0%	0.5%	-2.2%	3.2%
Asian	189	6	3.2%	96	0	0.0%	3.2%	0.7%	5.7%
Black or African American	189	9	4.8%	96	1	1.0%	3.7%	0.1%	7.4%
Native Hawaiian or Other Pacific Islander	189	0	0.0%	96	1	1.0%	-1.0%	-3.1%	1.0%
White	189	169	89.4%	96	93	96.9%	-7.5%	-13.1%	-1.9%
Other	189	2	1.1%	96	0	0.0%	1.1%	-0.4%	2.5%
Ethnicity									
Hispanic or Latino	189	15	7.9%	96	5	5.2%	2.7%	-3.2%	8.6%
Not Hispanic or Latino	189	174	92.1%	96	91	94.8%	-2.7%	-8.6%	3.2%
Nurick Classification[1]									
0	189	150	79.4%	96	85	88.5%	-9.2%	-17.8%	-0.6%
1	189	27	14.3%	96	9	9.4%	4.9%	-2.8%	12.6%
2	189	7	3.7%	96	2	2.1%	1.6%	-2.3%	5.5%
3	189	4	2.1%	96	0	0.0%	2.1%	0.1%	4.2%
4	189	0	0.0%	96	0	0.0%	0.0%	0.0%	0.0%
5	189	1	0.5%	96	0	0.0%	0.5%	-0.5%	1.6%
Symptomatic Cervical Disc Diagnosis									
No	189	0	0.0%	96	0	0.0%	0.0%	0.0%	0.0%
Yes	189	189	100.0%	96	96	100.0%	0.0%	0.0%	0.0%
Cervical Radiculopathy Diagnosis									
No	189	11	5.8%	96	2	2.1%	3.7%	-0.7%	8.1%
Yes	189	178	94.2%	96	94	97.9%	-3.7%	-8.1%	0.7%
Cervical Myelo-Radiculopathy Diagnosis									
No	189	161	85.2%	96	85	88.5%	-3.4%	-11.5%	4.8%
Yes	189	28	14.8%	96	11	11.5%	3.4%	-4.8%	11.5%
Previous Spine Surgeries									
No	189	165	87.3%	96	77	80.2%	7.1%	-2.2%	16.4%
Yes	189	24	12.7%	96	19	19.8%	-7.1%	-16.4%	2.2%
Relevant General Medical Conditions									
No	189	41	21.7%	96	23	24.0%	-2.3%	-12.6%	8.1%
Yes	189	148	78.3%	96	73	76.0%	2.3%	-8.1%	12.6%

	BAGUERA® C			Mobi-C			Group Difference		
	N	n	%	N	n	%	Dif	95% LB	95% UB
Current Medications for Cervical Spine									
No	189	48	25.4%	96	24	25.0%	0.4%	-10.3%	11.1%
Yes	189	141	74.6%	96	72	75.0%	-0.4%	-11.1%	10.3%

[1] Nurick Classification (Nurick, 1972): (0) Signs or symptoms of root involvement but without evidence of spinal cord disease; (1) Signs of spinal cord disease but no difficulty in walking; (2) Slight difficulty in walking which did not prevent full-time employment; (3) Difficulty in walking which prevented full-time employment or the ability to do all housework, but which was not so severe as to require someone else's help to walk; (4) Able to walk only with someone else's help or with the aid of a frame; (5) Chair bound or bedridden;
Source: Tables Baseline Demo.sas; Analyzed: 19JUN2026

Table 10 Baseline Work Status (Categorical). mITT Analysis Set

	BAGUERA® C			Mobi-C			Group Difference		
	N	n	%	N	n	%	Dif	95% LB	95% UB
Preoperative Disability Status									
No	189	178	94.2%	96	90	93.8%	0.4%	-5.5%	6.3%
Yes	189	11	5.8%	96	6	6.3%	-0.4%	-6.3%	5.5%
Preoperative Work Status									
Not working due to neck problem	189	11	5.8%	96	10	10.4%	-4.6%	-11.6%	2.4%
Not working voluntarily (retired, student, unemployed, etc.)	189	20	10.6%	96	7	7.3%	3.3%	-3.5%	10.1%
Not working other than neck problems (describe)	189	4	2.1%	96	1	1.0%	1.1%	-1.8%	4.0%
Working part time due to neck problem	189	4	2.1%	96	3	3.1%	-1.0%	-5.0%	3.0%
Working part time voluntarily	189	6	3.2%	96	6	6.3%	-3.1%	-8.5%	2.4%
Working full time	189	143	75.7%	96	68	70.8%	4.8%	-6.1%	15.8%
Other	189	1	0.5%	96	1	1.0%	-0.5%	-2.8%	1.8%

Source: Tables Baseline Demo.sas; Analyzed: 19JUN2026

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 mITT Analysis Set. Variables summarized include operative time, blood loss and length of stay. There was a statistically significant difference in estimated blood loss, in favor of BAGUERA® C in the female subgroup.

Table 11 Operative Continuous Variables. mITT Analysis Set

	BAGUERA® C						Mobi-C						Group Difference*			
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	Δ	LB	UB	p
All																
Duration of Surgery (min)	189	61.7	21.4	57.0	30.0	138.0	96	61.0	20.4	56.5	24.0	156.0	0.7	-4.4	5.8	0.493
Estimated Blood Loss (cc)	189	24.5	15.8	20.0	2.0	100.0	96	27.1	15.7	25.0	5.0	90.0	-2.6	-6.5	1.3	0.055
Hospital Length of Stay (days)	189	0.1	0.5	0.0	0.0	5.0	96	0.1	0.6	0.0	0.0	5.0	0.0	-0.1	0.1	0.360
Female																
Duration of Surgery (min)	86	57.9	20.6	53.0	30.0	138.0	38	58.0	17.6	51.5	24.0	97.0	-0.2	-7.2	6.9	0.346
Estimated Blood Loss (cc)	86	23.9	15.5	20.0	5.0	75.0	38	29.2	17.3	25.0	5.0	90.0	-5.2	-11.6	1.2	0.027
Male																
Duration of Surgery (min)	103	65.0	21.5	64.0	30.0	119.0	58	62.9	21.9	58.5	25.0	156.0	2.0	-5.0	9.0	0.287
Estimated Blood Loss (cc)	103	25.0	16.2	25.0	2.0	100.0	58	25.8	14.5	22.5	5.0	50.0	-0.8	-5.7	4.1	0.347

*Device group mean differences and 95% Confidence Intervals with Wilcoxon p-value
Source: Tables Operative 1L.sas; Analyzed: 19JUN2026

As evidenced in Table 12 below, the majority of procedures occurred at C5-C6 and C6-C7 for both the BAGUERA® C Cervical Disc Prosthesis subjects and the Mobi-C control subjects.

Table 12 Operative Characteristics (Categorical). mITT Analysis Set

	BAGUERA -C			Mobi-C			Group Difference		
	N	n	%	N	n	%	Diff.	95% LB	95% UB
Levels Treated									
C3-C4	189	3	1.6%	96	5	5.2%	-3.6%	-8.4%	1.2%
C4-C5	189	13	6.9%	96	4	4.2%	2.7%	-2.7%	8.1%
C5-C6	189	99	52.4%	96	49	51.0%	1.3%	-10.9%	13.6%
C6-C7	189	74	39.2%	96	38	39.6%	-0.4%	-12.4%	11.6%

Source: Tables Operative 1L.sas; Analyzed: 19JUN2026

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.

4. Safety and Effectiveness Results

a) Safety Results

The analysis of safety was based on the investigational cohort of 189 BAGUERA® C subjects and 96 control subjects through Month 24 evaluation. The key safety outcomes for this study are presented below in Tables 13 to 23. Adverse effects are reported in Tables 14 to 21.

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 procedure and implant-relatedness, seriousness, and if serious, whether the event was unanticipated.

Table 13 shows a summary of AE categories and rates between the investigational and control groups in the AT Analysis Set. Overall, similar rates of AEs occurred in the investigational group (61.9% - 117/189) and control group (69.8% - 67/96). SAEs that were considered "definitely" device-related were also comparable between the two groups, where 0% (0/189) of investigational subjects had "definitely" device-related SAEs, while 2.1% (2/96) control subjects had "definitely" device-related SAEs. Lastly, the rate of SAEs that were considered "definitely" procedure-related was 1.1% (2/189) in investigational subjects and 1.0% (1/96) in control subjects.

Table 13 Adverse Event Summary – AT Analysis Set (n=285)

	BAGUERA® C (N = 189)			Mobi-C (N = 96)		
	Events	Subjs	%[‖]	Events	Subjs	%[‖]
All	335	117	61.9%	164	67	69.8%
Device Related[†]	15	12	6.3%	10	9	9.4%
Device Related - Possibly	13	10	5.3%	5	5	5.2%
Device Related - Probably	2	2	1.1%	1	1	1.0%
Device Related - Definitely	0	0	0.0%	4	3	3.1%
Procedure Related[†]	53	40	21.2%	26	20	20.8%
Procedure Related - Possibly	21	17	9.0%	8	7	7.3%
Procedure Related - Probably	4	4	2.1%	1	1	1.0%
Procedure Related - Definitely	28	24	12.7%	17	13	13.5%
Device or Procedure Related[†]	61	43	22.8%	28	21	21.9%
Serious Adverse Events						
All	71	51	27.0%	28	23	24.0%
Device Related[†]	8	8	4.2%	5	4	4.2%
Device Related - Possibly	6	6	3.2%	1	1	1.0%
Device Related - Probably	2	2	1.1%	1	1	1.0%
Device Related - Definitely	0	0	0.0%	3	2	2.1%
Procedure Related[†]	5	5	2.6%	7	6	6.3%
Procedure Related - Possibly	2	2	1.1%	5	4	4.2%
Procedure Related - Probably	1	1	0.5%	1	1	1.0%
Procedure Related - Definitely	2	2	1.1%	1	1	1.0%
Device or Procedure Related[†]	11	11	5.8%	7	6	6.3%
AE by Severity						
Mild	203	87	46.0%	110	52	54.2%
Moderate	105	59	31.2%	42	24	25.0%
Severe	27	19	10.1%	12	10	10.4%
SAE by Severity						
Mild	26	19	10.1%	8	7	7.3%
Moderate	21	20	10.6%	9	9	9.4%
Severe	24	19	10.1%	11	10	10.4%

[†]Definite, probable, and possible.
[‖]Percent values listed reflect the percentage of subjects that experienced the specific type of adverse event (denominator is sample N noted in the column header). Source: Tables Safety - AE Summary.sas; Analyzed: 19JUN2026

All Adverse Events

Table 14 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 AT Analysis Set. The investigational group presented with 335 events occurring in 61.9% (117/189) of the 189 BAGUERA® C subjects, compared to 164 events occurring in 69.8% (67/96) of the 96 Mobi-C control subjects.

The most common AEs (rate of 5% or more) included: radiculopathy (including radicular arm pain) (investigational – 17.5%, 33/189; control – 14.6%, 14/96); cervical pain (no narcotic given) (investigational – 14.3%, 27/189; control – 14.6%, 14/96); shoulder pain (investigational – 11.1%, 21/189; control – 8.3%, 8/96); numbness/tingling, upper extremity (investigational – 7.9%, 15/189; control – 10.4%, 10/96); dysphagia (investigational – 6.3%, 12/189; control – 9.4%, 9/96); spasms (investigational – 5.8%, 11/189; control – 6.3%, 6/96); joint pain (investigational – 5.3%, 10/189; control – 7.3%, 7/96); headache (investigational – 5.3%, 10/189; control – 5.2%, 5/96); compressive neuropathy (investigational – 5.8%, 11/189; control – 2.1%, 2/96).

Table 14 All Adverse Events (AT Analysis Set, n=285)

	BAGUERA® C (N= 189)			Mobi-C (N= 96)			Diff.		
	AEs	Subjs	%*	AEs	Subjs	%*	%	LB†	UB†
All	**335**	**117**	**61.9%**	**164**	**67**	**69.8%**	**-7.9%**	**-19.4%**	**3.6%**
Blood and Lymphatic System Disorders	**0**	**0**	**0.0%**	**1**	**1**	**1.0%**	**-1.0%**		
Anemia	0	0	0.0%	1	1	1.0%	-1.0%		
Cardiac Disorders	**2**	**2**	**1.1%**	**1**	**1**	**1.0%**	**0.0%**		
Chest Pain	1	1	0.5%	1	1	1.0%	-0.5%		
Other Cardiac Disorders	1	1	0.5%	0	0	0.0%	0.5%		
Device (non system specific)	**1**	**1**	**0.5%**	**1**	**1**	**1.0%**	**-0.5%**		
Implant/Joint Noise	1	1	0.5%	0	0	0.0%	0.5%		
Device Delivery System Malfunction	0	0	0.0%	1	1	1.0%	-1.0%		
Ear and Labyrinth Disorders	**5**	**4**	**2.1%**	**2**	**2**	**2.1%**	**0.0%**		
Vertigo	5	4	2.1%	2	2	2.1%	0.0%		
Endocrine Disorders	**5**	**5**	**2.6%**	**0**	**0**	**0.0%**	**2.6%**		
Diabetes Mellitus	4	4	2.1%	0	0	0.0%	2.1%		
Other Endocrine Disorder	1	1	0.5%	0	0	0.0%	0.5%		
Eye Disorders	**1**	**1**	**0.5%**	**2**	**2**	**2.1%**	**-1.6%**		
Blurred Vision	0	0	0.0%	1	1	1.0%	-1.0%		
Conjunctivitis	1	1	0.5%	0	0	0.0%	0.5%		
Retinal Detachment	0	0	0.0%	1	1	1.0%	-1.0%		
Gastrointestinal Disorders	**13**	**13**	**6.9%**	**10**	**10**	**10.4%**	**-3.5%**	**-10.6%**	**3.6%**
Colitis	0	0	0.0%	1	1	1.0%	-1.0%		
Dysphagia	12	12	6.3%	9	9	9.4%	-3.0%	-9.8%	3.8%
Gastroesophageal Reflux Disease	1	1	0.5%	0	0	0.0%	0.5%		
General Disorders and Administrative Site Conditions	**2**	**2**	**1.1%**	**0**	**0**	**0.0%**	**1.1%**		
General Pain, Not Specified Elsewhere	1	1	0.5%	0	0	0.0%	0.5%		
Hernia	1	1	0.5%	0	0	0.0%	0.5%		
Immune System Disorders	**5**	**5**	**2.6%**	**1**	**1**	**1.0%**	**1.6%**		
Allergic Reaction	1	1	0.5%	1	1	1.0%	-0.5%		
Anaphylaxis	1	1	0.5%	0	0	0.0%	0.5%		
Foreign Body Reaction, Non-Implant	1	1	0.5%	0	0	0.0%	0.5%		
Inflammatory Condition	1	1	0.5%	0	0	0.0%	0.5%		
Other Immune System Disorders	1	1	0.5%	0	0	0.0%	0.5%		
Infections and Infestations	**13**	**11**	**5.8%**	**10**	**9**	**9.4%**	**-3.6%**	**-10.3%**	**3.2%**
Appendicitis	1	1	0.5%	0	0	0.0%	0.5%		
Infection, Surgical Site	2	2	1.1%	0	0	0.0%	1.1%		

	BAGUERA® C (N= 189)			Mobi-C (N= 96)			Diff.		
	AEs	Subjs	%*	AEs	Subjs	%*	%	LB†	UB†
Sinusitis	1	1	0.5%	1	1	1.0%	-0.5%		
Rash	0	0	0.0%	2	2	2.1%	-2.1%		
COVID-19 Infection	6	6	3.2%	4	4	4.2%	-1.0%		
Abscess, Oral	1	1	0.5%	0	0	0.0%	0.5%		
Herpes zoster	0	0	0.0%	1	1	1.0%	-1.0%		
Influenza	1	1	0.5%	0	0	0.0%	0.5%		
Respiratory Tract Infection	1	1	0.5%	0	0	0.0%	0.5%		
Urinary Tract Infection	0	0	0.0%	1	1	1.0%	-1.0%		
Rhinoviral Infection	0	0	0.0%	1	1	1.0%	-1.0%		
Metabolism and Nutrition Disorders	**3**	**3**	**1.6%**	**1**	**1**	**1.0%**	**0.5%**		
Decreased appetite	1	1	0.5%	0	0	0.0%	0.5%		
Dehydration	1	1	0.5%	0	0	0.0%	0.5%		
Hypercholesteremia	0	0	0.0%	1	1	1.0%	-1.0%		
Hyperlipidemia	1	1	0.5%	0	0	0.0%	0.5%		
Musculoskeletal and Connective Tissue Disorders	**142**	**75**	**39.7%**	**73**	**39**	**40.6%**	**-0.9%**	**-13.0%**	**11.1%**
Arm Pain (not radicular)	7	7	3.7%	6	6	6.3%	-2.5%	-8.1%	3.0%
Cervical pain (no narcotic given)	28	27	14.3%	15	14	14.6%	-0.3%	-8.9%	8.3%
Cervical pain (narcotic given)	1	1	0.5%	0	0	0.0%	0.5%		
Joint pain	11	10	5.3%	8	7	7.3%	-2.0%	-8.1%	4.1%
Joint stiffness	1	1	0.5%	1	1	1.0%	-0.5%		
Lumbar pain	11	10	5.3%	5	5	5.2%	0.1%	-5.4%	5.6%
Neck stiffness	2	2	1.1%	3	3	3.1%	-2.1%		
Other Musculoskeletal Pain, Specify Location	11	9	4.8%	1	1	1.0%	3.7%		
Spasms	11	11	5.8%	6	6	6.3%	-0.4%	-6.3%	5.5%
Cervical Foraminal Stenosis	3	3	1.6%	1	1	1.0%	0.5%		
Lumbar Spinal Stenosis	1	1	0.5%	1	1	1.0%	-0.5%		
Muscle Rupture	1	1	0.5%	3	3	3.1%	-2.6%		
Muscle Strain	0	0	0.0%	1	1	1.0%	-1.0%		
Muscle Tension	0	0	0.0%	2	2	2.1%	-2.1%		
Muscle Weakness, Lower Extremity	2	2	1.1%	0	0	0.0%	1.1%		
Muscle Weakness, Upper Extremity	3	3	1.6%	2	2	2.1%	-0.5%		
Osteoarthritis	3	3	1.6%	0	0	0.0%	1.6%		
Plantar Fasciitis	1	1	0.5%	1	1	1.0%	-0.5%		
Shoulder Blade Pain	5	5	2.6%	2	2	2.1%	0.6%		
Shoulder Pain	26	21	11.1%	9	8	8.3%	2.8%	-4.3%	9.9%
Thoracic Pain	2	2	1.1%	2	2	2.1%	-1.0%		

	BAGUERA® C (N= 189)			Mobi-C (N= 96)			Diff.		
	AEs	Subjs	%*	AEs	Subjs	%*	%	LB†	UB†
Trapezius Pain	6	5	2.6%	1	1	1.0%	1.6%		
Trigger Finger	2	2	1.1%	0	0	0.0%	1.1%		
Fracture, Any Bone	4	4	2.1%	0	0	0.0%	2.1%		
Tendonitis	0	0	0.0%	2	1	1.0%	-1.0%		
Other Musculoskeletal and Connective Tissue Disorder	0	0	0.0%	1	1	1.0%	-1.0%		
Nervous System Disorders	**93**	**64**	**33.9%**	**41**	**33**	**34.4%**	**-0.5%**	**-12.2%**	**11.1%**
Compressive neuropathy	12	11	5.8%	3	2	2.1%	3.7%		
Dizziness	1	1	0.5%	0	0	0.0%	0.5%		
Headache	10	10	5.3%	5	5	5.2%	0.1%	-5.4%	5.6%
Neuralgia	2	2	1.1%	0	0	0.0%	1.1%		
Neurological deterioration (motor, sensory or reflex)	0	0	0.0%	1	1	1.0%	-1.0%		
Numbness/Tingling, unspecified	0	0	0.0%	1	1	1.0%	-1.0%		
Paresthesia	1	1	0.5%	0	0	0.0%	0.5%		
Radiculopathy (including radicular arm pain)	37	33	17.5%	14	14	14.6%	2.9%	-6.0%	11.8%
Temporary or permanent nerve damage	0	0	0.0%	1	1	1.0%	-1.0%		
Weakness	0	0	0.0%	2	2	2.1%	-2.1%		
Numbness/Tingling, Upper Extremity	17	15	7.9%	11	10	10.4%	-2.5%	-9.7%	4.7%
Numbness/Tingling, Lower Extremity	5	5	2.6%	1	1	1.0%	1.6%		
Numbness/Tingling, Oral	0	0	0.0%	1	1	1.0%	-1.0%		
Peripheral Neuropathy	5	5	2.6%	1	1	1.0%	1.6%		
Thoracic Outlet Syndrome	3	2	1.1%	0	0	0.0%	1.1%		
Psychiatric Disorders	**6**	**6**	**3.2%**	**4**	**3**	**3.1%**	**0.0%**		
Anxiety Disorders	2	2	1.1%	1	1	1.0%	0.0%		
Depression	1	1	0.5%	1	1	1.0%	-0.5%		
Insomnia	1	1	0.5%	1	1	1.0%	-0.5%		
Other Psychiatric Disorder	2	2	1.1%	1	1	1.0%	0.0%		
Renal and Urinary Disorders	**3**	**3**	**1.6%**	**0**	**0**	**0.0%**	**1.6%**		
Renal Calculi	3	3	1.6%	0	0	0.0%	1.6%		
Reproductive System and Breast Disorders	**9**	**7**	**3.7%**	**2**	**2**	**2.1%**	**1.6%**		
Polycystic Ovarian Syndrome	1	1	0.5%	0	0	0.0%	0.5%		
Uterine Neoplasm	4	4	2.1%	0	0	0.0%	2.1%		
Uterovaginal prolapse	1	1	0.5%	0	0	0.0%	0.5%		
Other Reproductive System and Breast Disorder	3	2	1.1%	2	2	2.1%	-1.0%		
Respiratory, Thoracic and Mediastinal Disorders	**3**	**3**	**1.6%**	**0**	**0**	**0.0%**	**1.6%**		
Sleep apnea	1	1	0.5%	0	0	0.0%	0.5%		
Hemoptysis	1	1	0.5%	0	0	0.0%	0.5%		

	BAGUERA® C (N= 189)			Mobi-C (N= 96)			Diff.		
	AEs	Subjs	%*	AEs	Subjs	%*	%	LB†	UB†
Other Respiratory, Thoracic and Mediastinal Disorders Disorder	1	1	0.5%	0	0	0.0%	0.5%		
Skin and Subcutaneous Tissue Disorders	**10**	**9**	**4.8%**	**4**	**4**	**4.2%**	**0.6%**		
Hematoma	1	1	0.5%	0	0	0.0%	0.5%		
Itching/Pruritus	0	0	0.0%	2	2	2.1%	-2.1%		
Urticaria	1	1	0.5%	0	0	0.0%	0.5%		
Wound complications (e.g., dehiscence, bruising) and soft tissue damage	7	6	3.2%	2	2	2.1%	1.1%		
Other Skin and Subcutaneous Tissue Disorder	1	1	0.5%	0	0	0.0%	0.5%		
Vascular Disorders	**5**	**5**	**2.6%**	**5**	**5**	**5.2%**	**-2.6%**	**-7.6%**	**2.4%**
Angioedema	0	0	0.0%	2	2	2.1%	-2.1%		
Thromboembolic Event	0	0	0.0%	1	1	1.0%	-1.0%		
Hypertension	3	3	1.6%	2	2	2.1%	-0.5%		
Syncope/Fainting	1	1	0.5%	0	0	0.0%	0.5%		
Other Vascular Disorder	1	1	0.5%	0	0	0.0%	0.5%		
Other Complications/Events	**14**	**13**	**6.9%**	**6**	**6**	**6.3%**	**0.6%**	**-5.4%**	**6.7%**
Cancer	2	2	1.1%	1	1	1.0%	0.0%		
Adverse Reaction to Medication	1	1	0.5%	0	0	0.0%	0.5%		
Other Event, Describe	4	4	2.1%	0	0	0.0%	2.1%		
Accident and injury	7	6	3.2%	4	4	4.2%	-1.0%		
Peripheral Swelling	0	0	0.0%	1	1	1.0%	-1.0%		

*Percentage of subjects experiencing specific event.

† 95% Asymptotic CI reported when at least five subjects experienced the AE and at least five subjects did not experience the AE.
Source: Tables Safety.sas; Analyzed: 19JUN2026

All Adverse Events by Time Course

Table 15 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 12 and Month 24 for the control group.

Table 15 All Adverse Events (Time course) – AT Analysis Set N=285

	Days Post-Op															
	<0		0-2		2-30		30-90		90-180		180-365		365-730		Total	
	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C
All	**0**	**0**	**21**	**16**	**37**	**13**	**66**	**26**	**54**	**26**	**63**	**36**	**94**	**47**	**335**	**164**
Blood and Lymphatic System Disorders	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**1**
Anemia	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1
Cardiac Disorders	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**0**	**0**	**1**	**1**	**0**	**0**	**2**	**1**
Chest Pain	0	0	0	0	0	0	1	0	0	0	0	1	0	0	1	1
Other Cardiac Disorders	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0
Device (non system specific)	**0**	**0**	**0**	**1**	**0**	**0**	**1**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**1**
Implant/Joint Noise	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	0
Device Delivery System Malfunction	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1
Ear and Labyrinth Disorders	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**0**	**1**	**3**	**0**	**1**	**1**	**5**	**2**
Vertigo	0	0	0	0	0	0	1	0	0	1	3	0	1	1	5	2
Endocrine Disorders	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**1**	**0**	**0**	**0**	**3**	**0**	**5**	**0**
Diabetes Mellitus	0	0	0	0	0	0	1	0	1	0	0	0	2	0	4	0
Other Endocrine Disorder	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0
Eye Disorders	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**0**	**1**	**0**	**0**	**1**	**1**	**2**
Blurred Vision	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1
Conjunctivitis	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0
Retinal Detachment	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1
Gastrointestinal Disorders	**0**	**0**	**10**	**7**	**2**	**0**	**0**	**0**	**0**	**0**	**1**	**2**	**0**	**1**	**13**	**10**
Colitis	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1
Dysphagia	0	0	10	7	1	0	0	0	0	0	1	2	0	0	12	9
Gastroesophageal Reflux Disease	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1	0
General Disorders and Administrative Site Conditions	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**2**	**0**	**2**	**0**
General Pain, Not Specified Elsewhere	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0
Hernia	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0
Immune System Disorders	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**1**	**0**	**3**	**1**	**5**	**1**
Allergic Reaction	0	0	0	0	0	0	0	0	0	0	1	0	0	1	1	1
Anaphylaxis	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0
Foreign Body Reaction, Non-Implant	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1	0
Inflammatory Condition	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0
Other Immune System Disorders	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0
Infections and Infestations	**0**	**0**	**0**	**1**	**2**	**0**	**5**	**3**	**3**	**1**	**2**	**3**	**1**	**2**	**13**	**10**
Appendicitis	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0
Infection, Surgical Site	0	0	0	0	1	0	0	0	1	0	0	0	0	0	2	0

	Days Post-Op															
	<0		0-2		2-30		30-90		90-180		180-365		365-730		Total	
	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C
Sinusitis	0	0	0	0	0	0	1	1	0	0	0	0	0	0	1	1
Rash	0	0	0	1	0	0	0	0	0	1	0	0	0	0	0	2
COVID-19 Infection	0	0	0	0	0	0	3	1	2	0	1	2	0	1	6	4
Abscess, Oral	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1	0
Herpes zoster	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1
Influenza	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	0
Respiratory Tract Infection	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0
Urinary Tract Infection	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1
Rhinoviral Infection	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1
Metabolism and Nutrition Disorders	**0**	**0**	**0**	**0**	**1**	**0**	**0**	**1**	**0**	**0**	**0**	**0**	**2**	**0**	**3**	**1**
Decreased appetite	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1	0
Dehydration	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0
Hypercholesteremia	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1
Hyperlipidemia	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0
Musculoskeletal and Connective Tissue Disorders	**0**	**0**	**5**	**4**	**15**	**5**	**31**	**11**	**25**	**16**	**33**	**13**	**33**	**24**	**142**	**73**
Arm Pain (not radicular)	0	0	0	1	0	0	0	2	1	0	1	1	5	2	7	6
Cervical pain (no narcotic given)	0	0	1	2	6	0	4	3	6	5	8	3	3	2	28	15
Cervical pain (narcotic given)	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1	0
Joint pain	0	0	0	0	0	0	1	1	4	2	1	1	5	4	11	8
Joint stiffness	0	0	0	0	0	0	1	0	0	0	0	0	0	1	1	1
Lumbar pain	0	0	0	1	0	0	5	0	3	2	1	2	2	0	11	5
Neck stiffness	0	0	0	0	0	0	0	0	0	0	1	2	1	1	2	3
Other Musculoskeletal Pain, Specify Location	0	0	0	0	1	0	1	0	2	0	3	0	4	1	11	1
Spasms	0	0	2	0	1	1	3	0	2	1	3	1	0	3	11	6
Cervical Foraminal Stenosis	0	0	0	0	1	0	0	0	0	1	1	0	1	0	3	1
Lumbar Spinal Stenosis	0	0	0	0	0	1	1	0	0	0	0	0	0	0	1	1
Muscle Rupture	0	0	0	0	0	0	0	1	0	0	1	1	0	1	1	3
Muscle Strain	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1
Muscle Tension	0	0	0	0	0	0	0	1	0	0	0	0	0	1	0	2
Muscle Weakness, Lower Extremity	0	0	0	0	1	0	0	0	0	0	1	0	0	0	2	0
Muscle Weakness, Upper Extremity	0	0	0	0	0	1	1	0	0	0	1	0	1	1	3	2
Osteoarthritis	0	0	0	0	0	0	1	0	1	0	0	0	1	0	3	0
Plantar Fasciitis	0	0	0	0	1	0	0	1	0	0	0	0	0	0	1	1
Shoulder Blade Pain	0	0	0	0	1	0	2	1	1	1	1	0	0	0	5	2
Shoulder Pain	0	0	2	0	1	2	7	0	3	3	6	0	7	4	26	9

	Days Post-Op															
	<0		0-2		2-30		30-90		90-180		180-365		365-730		Total	
	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C
Thoracic Pain	0	0	0	0	0	0	1	1	1	0	0	0	0	1	2	2
Trapezius Pain	0	0	0	0	1	0	2	0	0	1	2	0	1	0	6	1
Trigger Finger	0	0	0	0	0	0	0	0	0	0	0	0	2	0	2	0
Fracture, Any Bone	0	0	0	0	0	0	1	0	1	0	2	0	0	0	4	0
Tendonitis	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	2
Other Musculoskeletal and Connective Tissue Disorder	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1
Nervous System Disorders	**0**	**0**	**5**	**2**	**8**	**4**	**18**	**6**	**18**	**4**	**15**	**13**	**29**	**12**	**93**	**41**
Compressive neuropathy	0	0	1	0	0	2	1	0	4	0	2	1	4	0	12	3
Dizziness	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0
Headache	0	0	2	1	1	0	1	0	0	0	3	0	3	4	10	5
Neuralgia	0	0	0	0	1	0	1	0	0	0	0	0	0	0	2	0
Neurological deterioration (motor, sensory or reflex)	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1
numbness/tingling	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1
Paresthesia	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1	0
Radiculopathy (including radicular arm pain)	0	0	0	0	5	0	9	2	4	2	6	6	13	4	37	14
Temporary or permanent nerve damage	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1
Weakness	0	0	0	0	0	0	0	1	0	0	0	0	0	1	0	2
Numbness/Tingling, Upper Extremity	0	0	0	0	0	1	2	3	7	1	2	4	6	2	17	11
Numbness/Tingling, Lower Extremity	0	0	0	0	0	0	1	0	3	1	1	0	0	0	5	1
Numbness/Tingling, Oral	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1
Peripheral Neuropathy	0	0	1	0	1	1	2	0	0	0	0	0	1	0	5	1
Thoracic Outlet Syndrome	0	0	0	0	0	0	1	0	0	0	1	0	1	0	3	0
Psychiatric Disorders	**0**	**0**	**0**	**0**	**1**	**0**	**1**	**1**	**2**	**2**	**1**	**0**	**1**	**1**	**6**	**4**
Anxiety Disorders	0	0	0	0	0	0	0	0	1	0	0	0	1	1	2	1
Depression	0	0	0	0	0	0	1	0	0	1	0	0	0	0	1	1
Insomnia	0	0	0	0	1	0	0	1	0	0	0	0	0	0	1	1
Other Psychiatric Disorder	0	0	0	0	0	0	0	0	1	1	1	0	0	0	2	1
Renal and Urinary Disorders	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**2**	**0**	**3**	**0**
Renal Calculi	0	0	0	0	0	0	0	0	0	0	1	0	2	0	3	0
Reproductive System and Breast Disorders	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**2**	**0**	**1**	**0**	**5**	**2**	**9**	**2**
Polycystic Ovarian Syndrome	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	0
Uterine Neoplasm	0	0	0	0	0	0	0	0	2	0	1	0	1	0	4	0
Uterovaginal prolapse	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0
Other Reproductive System and Breast Disorder	0	0	0	0	0	0	0	0	0	0	0	0	3	2	3	2

	Days Post-Op															
	<0		0-2		2-30		30-90		90-180		180-365		365-730		Total	
	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C
Respiratory, Thoracic and Mediastinal Disorders	**0**	**0**	**1**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**1**	**0**	**3**	**0**
Sleep apnea	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0
Hemoptysis	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1	0
Other Respiratory, Thoracic and Mediastinal Disorders Disorder	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0
Skin and Subcutaneous Tissue Disorders	**0**	**0**	**0**	**1**	**6**	**2**	**2**	**0**	**0**	**0**	**0**	**1**	**2**	**0**	**10**	**4**
Hematoma	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	0
Itching/Pruritus	0	0	0	0	0	1	0	0	0	0	0	1	0	0	0	2
Urticaria	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0
Wound complications (e.g., dehiscence, bruising) and soft tissue damage	0	0	0	1	6	1	1	0	0	0	0	0	0	0	7	2
Other Skin and Subcutaneous Tissue Disorder	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0
Vascular Disorders	**0**	**0**	**0**	**0**	**1**	**1**	**1**	**1**	**1**	**1**	**1**	**1**	**1**	**1**	**5**	**5**
Angioedema	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	2
Thromboembolic Event	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1
Hypertension	0	0	0	0	1	0	0	0	1	0	0	1	1	1	3	2
Syncope/Fainting	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	0
Other Vascular Disorder	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0
Other Complications/Events	**0**	**0**	**0**	**0**	**1**	**1**	**3**	**2**	**1**	**1**	**1**	**2**	**8**	**0**	**14**	**6**
Cancer	0	0	0	0	0	1	0	0	0	0	0	0	2	0	2	1
Adverse Reaction to Medication	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1	0
Other Event, Describe	0	0	0	0	0	0	0	0	0	0	0	0	4	0	4	0
Accident and injury	0	0	0	0	0	0	3	2	1	1	1	1	2	0	7	4
Peripheral Swelling	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1

Source: Tables Safety.sas; Analyzed: 19JUN2026

All Adverse Events by Severity

Table 16 presents the AEs observed in the investigational group stratified by severity. These AEs were classified as Mild, Moderate, or Severe events. Overall, there were 203 mild AEs, 105 moderate AEs, and 27 Severe AEs reported in the BAGUERA® C group in the AT population (N=189).

Table 16 All Adverse Events (Severity) – BAGUERA® C Investigational (AT Analysis Set, N=189)

	Mild		Moderate		Severe		Total
	AEs	%*	AEs	%*	AEs	%*	AEs
All	**203**	**60.6%**	**105**	**31.3%**	**27**	**8.1%**	**335**
Cardiac Disorders	**1**	**50.0%**	**0**	**0.0%**	**1**	**50.0%**	**2**
Chest Pain	1	100.0%	0	0.0%	0	0.0%	1
Other Cardiac Disorders	0	0.0%	0	0.0%	1	100.0%	1
Device (non-system specific)	**1**	**100.0%**	**0**	**0.0%**	**0**	**0.0%**	**1**
Implant/Joint Noise	1	100.0%	0	0.0%	0	0.0%	1
Ear and Labyrinth Disorders	**5**	**100.0%**	**0**	**0.0%**	**0**	**0.0%**	**5**
Vertigo	5	100.0%	0	0.0%	0	0.0%	5
Endocrine Disorders	**3**	**60.0%**	**2**	**40.0%**	**0**	**0.0%**	**5**
Diabetes Mellitus	3	75.0%	1	25.0%	0	0.0%	4
Other Endocrine Disorder	0	0.0%	1	100.0%	0	0.0%	1
Eye Disorders	**1**	**100.0%**	**0**	**0.0%**	**0**	**0.0%**	**1**
Conjunctivitis	1	100.0%	0	0.0%	0	0.0%	1
Gastrointestinal Disorders	**11**	**84.6%**	**2**	**15.4%**	**0**	**0.0%**	**13**
Dysphagia	10	83.3%	2	16.7%	0	0.0%	12
Gastroesophageal Reflux Disease	1	100.0%	0	0.0%	0	0.0%	1
General Disorders and Admin Site Conditions	**1**	**50.0%**	**1**	**50.0%**	**0**	**0.0%**	**2**
General Pain, Not Specified Elsewhere	1	100.0%	0	0.0%	0	0.0%	1
Hernia	0	0.0%	1	100.0%	0	0.0%	1
Immune System Disorders	**2**	**40.0%**	**2**	**40.0%**	**1**	**20.0%**	**5**
Allergic Reaction	1	100.0%	0	0.0%	0	0.0%	1
Anaphylaxis	1	100.0%	0	0.0%	0	0.0%	1
Foreign Body Reaction, Non-Implant	0	0.0%	0	0.0%	1	100.0%	1
Inflammatory Condition	0	0.0%	1	100.0%	0	0.0%	1
Other Immune System Disorders	0	0.0%	1	100.0%	0	0.0%	1
Infections and Infestations	**10**	**76.9%**	**2**	**15.4%**	**1**	**7.7%**	**13**
Appendicitis	1	100.0%	0	0.0%	0	0.0%	1
Infection, Surgical Site	1	50.0%	0	0.0%	1	50.0%	2
Sinusitis	1	100.0%	0	0.0%	0	0.0%	1
COVID-19 Infection	5	83.3%	1	16.7%	0	0.0%	6
Abscess, Oral	0	0.0%	1	100.0%	0	0.0%	1
Influenza	1	100.0%	0	0.0%	0	0.0%	1
Respiratory Tract Infection	1	100.0%	0	0.0%	0	0.0%	1
Metabolism and Nutrition Disorders	**3**	**100.0%**	**0**	**0.0%**	**0**	**0.0%**	**3**
Decreased appetite	1	100.0%	0	0.0%	0	0.0%	1
Dehydration	1	100.0%	0	0.0%	0	0.0%	1
Hyperlipidemia	1	100.0%	0	0.0%	0	0.0%	1
Musculoskeletal and Connective Tissue Disorders	**90**	**63.4%**	**41**	**28.9%**	**11**	**7.7%**	**142**
Arm Pain (not radicular)	4	57.1%	2	28.6%	1	14.3%	7

	Mild		Moderate		Severe		Total
	AEs	%*	AEs	%*	AEs	%*	AEs
Cervical pain (no narcotic given)	21	75.0%	7	25.0%	0	0.0%	28
Cervical pain (narcotic given)	0	0.0%	1	100.0%	0	0.0%	1
Joint pain	5	45.5%	5	45.5%	1	9.1%	11
Joint stiffness	1	100.0%	0	0.0%	0	0.0%	1
Lumbar pain	8	72.7%	3	27.3%	0	0.0%	11
Neck stiffness	2	100.0%	0	0.0%	0	0.0%	2
Other Musculoskeletal Pain, Specify Location	8	72.7%	3	27.3%	0	0.0%	11
Spasms	8	72.7%	2	18.2%	1	9.1%	11
Cervical Foraminal Stenosis	0	0.0%	0	0.0%	3	100.0%	3
Lumbar Spinal Stenosis	1	100.0%	0	0.0%	0	0.0%	1
Muscle Rupture	0	0.0%	0	0.0%	1	100.0%	1
Muscle Weakness, Lower Extremity	2	100.0%	0	0.0%	0	0.0%	2
Muscle Weakness, Upper Extremity	1	33.3%	2	66.7%	0	0.0%	3
Osteoarthritis	0	0.0%	1	33.3%	2	66.7%	3
Plantar Fasciitis	1	100.0%	0	0.0%	0	0.0%	1
Shoulder Blade Pain	3	60.0%	2	40.0%	0	0.0%	5
Shoulder Pain	16	61.5%	8	30.8%	2	7.7%	26
Thoracic Pain	2	100.0%	0	0.0%	0	0.0%	2
Trapezius Pain	5	83.3%	1	16.7%	0	0.0%	6
Trigger Finger	1	50.0%	1	50.0%	0	0.0%	2
Fracture, Any Bone	1	25.0%	3	75.0%	0	0.0%	4
Nervous System Disorders	**47**	**50.5%**	**37**	**39.8%**	**9**	**9.7%**	**93**
Compressive neuropathy	6	50.0%	4	33.3%	2	16.7%	12
Dizziness	1	100.0%	0	0.0%	0	0.0%	1
Headache	6	60.0%	4	40.0%	0	0.0%	10
Neuralgia	0	0.0%	2	100.0%	0	0.0%	2
Paresthesia	1	100.0%	0	0.0%	0	0.0%	1
Radiculopathy (including radicular arm pain)	15	40.5%	15	40.5%	7	18.9%	37
Numbness/Tingling, Upper Extremity	13	76.5%	4	23.5%	0	0.0%	17
Numbness/Tingling, Lower Extremity	3	60.0%	2	40.0%	0	0.0%	5
Peripheral Neuropathy	2	40.0%	3	60.0%	0	0.0%	5
Thoracic Outlet Syndrome	0	0.0%	3	100.0%	0	0.0%	3
Psychiatric Disorders	**4**	**66.7%**	**2**	**33.3%**	**0**	**0.0%**	**6**
Anxiety Disorders	2	100.0%	0	0.0%	0	0.0%	2
Depression	1	100.0%	0	0.0%	0	0.0%	1
Insomnia	0	0.0%	1	100.0%	0	0.0%	1
Other Psychiatric Disorder	1	50.0%	1	50.0%	0	0.0%	2
Renal and Urinary Disorders	**2**	**66.7%**	**1**	**33.3%**	**0**	**0.0%**	**3**
Renal Calculi	2	66.7%	1	33.3%	0	0.0%	3
Reproductive System and Breast Disorders	**6**	**66.7%**	**2**	**22.2%**	**1**	**11.1%**	**9**
Polycystic Ovarian Syndrome	1	100.0%	0	0.0%	0	0.0%	1
Uterine Neoplasm	3	75.0%	1	25.0%	0	0.0%	4
Uterovaginal prolapse	0	0.0%	0	0.0%	1	100.0%	1
Other Reproductive System and Breast Disorder	2	66.7%	1	33.3%	0	0.0%	3
Respiratory, Thoracic and Mediastinal Disorders	**1**	**33.3%**	**1**	**33.3%**	**1**	**33.3%**	**3**
Sleep apnea	0	0.0%	1	100.0%	0	0.0%	1
Hemoptysis	0	0.0%	0	0.0%	1	100.0%	1

	Mild		Moderate		Severe		Total
	AEs	%*	AEs	%*	AEs	%*	AEs
Other Respiratory, Thoracic and Mediastinal Disorders Disorder	1	100.0%	0	0.0%	0	0.0%	1
Skin and Subcutaneous Tissue Disorders	**5**	**50.0%**	**5**	**50.0%**	**0**	**0.0%**	**10**
Hematoma	1	100.0%	0	0.0%	0	0.0%	1
Urticaria	1	100.0%	0	0.0%	0	0.0%	1
Wound complications (e.g., dehiscence, bruising) and soft tissue damage	2	28.6%	5	71.4%	0	0.0%	7
Other Skin and Subcutaneous Tissue Disorder	1	100.0%	0	0.0%	0	0.0%	1
Vascular Disorders	**3**	**60.0%**	**1**	**20.0%**	**1**	**20.0%**	**5**
Hypertension	2	66.7%	1	33.3%	0	0.0%	3
Syncope/Fainting	1	100.0%	0	0.0%	0	0.0%	1
Other Vascular Disorder	0	0.0%	0	0.0%	1	100.0%	1
Other Complications/Events	**7**	**50.0%**	**6**	**42.9%**	**1**	**7.1%**	**14**
Cancer	0	0.0%	1	50.0%	1	50.0%	2
Adverse Reaction to Medication	0	0.0%	1	100.0%	0	0.0%	1
Other Event, Describe	3	75.0%	1	25.0%	0	0.0%	4
Accident and injury	4	57.1%	3	42.9%	0	0.0%	7

*Percentage of total events for that specific AE code. Row percentages will sum to 100%.
Source: Tables Safety.sas; Analyzed: 19JUN2026

Table 17 presents the AEs observed in the control group stratified by severity. These AEs were classified as Mild, Moderate, or Severe events. Overall, there were 110 mild AEs, 42 moderate AEs, and 12 Severe AEs reported in the Mobi-C control group in the AT population (N=96).

Table 17 All Adverse Events (Severity) – Mobi-C Control (AT Analysis Set, N=96)

	Mild		Moderate		Severe		Total
	Events	%*	Events	%*	Events	%*	Events
All	**110**	**67.1%**	**42**	**25.6%**	**12**	**7.3%**	**164**
Blood and Lymphatic System Disorders	**1**	**100.0%**	**0**	**0.0%**	**0**	**0.0%**	**1**
Anemia	1	100.0%	0	0.0%	0	0.0%	1
Cardiac Disorders	**1**	**100.0%**	**0**	**0.0%**	**0**	**0.0%**	**1**
Chest Pain	1	100.0%	0	0.0%	0	0.0%	1
Device (non system specific)	**1**	**100.0%**	**0**	**0.0%**	**0**	**0.0%**	**1**
Device Delivery System Malfunction	1	100.0%	0	0.0%	0	0.0%	1
Ear and Labyrinth Disorders	**2**	**100.0%**	**0**	**0.0%**	**0**	**0.0%**	**2**
Vertigo	2	100.0%	0	0.0%	0	0.0%	2
Eye Disorders	**1**	**50.0%**	**1**	**50.0%**	**0**	**0.0%**	**2**
Blurred Vision	1	100.0%	0	0.0%	0	0.0%	1
Retinal Detachment	0	0.0%	1	100.0%	0	0.0%	1
Gastrointestinal Disorders	**8**	**80.0%**	**1**	**10.0%**	**1**	**10.0%**	**10**
Colitis	1	100.0%	0	0.0%	0	0.0%	1
Dysphagia	7	77.8%	1	11.1%	1	11.1%	9
Immune System Disorders	**0**	**0.0%**	**1**	**100.0%**	**0**	**0.0%**	**1**
Allergic Reaction	0	0.0%	1	100.0%	0	0.0%	1
Infections and Infestations	**8**	**80.0%**	**2**	**20.0%**	**0**	**0.0%**	**10**

	Mild		Moderate		Severe		Total
	Events	%*	Events	%*	Events	%*	Events
Sinusitis	1	100.0%	0	0.0%	0	0.0%	1
Rash	2	100.0%	0	0.0%	0	0.0%	2
COVID-19 Infection	2	50.0%	2	50.0%	0	0.0%	4
Herpes zoster	1	100.0%	0	0.0%	0	0.0%	1
Urinary Tract Infection	1	100.0%	0	0.0%	0	0.0%	1
Rhinoviral Infection	1	100.0%	0	0.0%	0	0.0%	1
Metabolism and Nutrition Disorders	**0**	**0.0%**	**1**	**100.0%**	**0**	**0.0%**	**1**
Hypercholesteremia	0	0.0%	1	100.0%	0	0.0%	1
Musculoskeletal and Connective Tissue Disorders	**48**	**65.8%**	**19**	**26.0%**	**6**	**8.2%**	**73**
Arm Pain (not radicular)	4	66.7%	1	16.7%	1	16.7%	6
Cervical Foraminal Stenosis	1	100.0%	0	0.0%	0	0.0%	1
Cervical pain (no narcotic given)	11	73.3%	1	6.7%	3	20.0%	15
Joint pain	3	37.5%	5	62.5%	0	0.0%	8
Joint stiffness	1	100.0%	0	0.0%	0	0.0%	1
Lumbar pain	5	100.0%	0	0.0%	0	0.0%	5
Neck stiffness	1	33.3%	2	66.7%	0	0.0%	3
Other Musculoskeletal Pain, unspecified	1	100.0%	0	0.0%	0	0.0%	1
Lumbar Spinal Stenosis	0	0.0%	0	0.0%	1	100.0%	1
Muscle Rupture	1	33.3%	1	33.3%	1	33.3%	3
Muscle Strain	1	100.0%	0	0.0%	0	0.0%	1
Muscle Tension	2	100.0%	0	0.0%	0	0.0%	2
Muscle Weakness, Upper Extremity	2	100.0%	0	0.0%	0	0.0%	2
Plantar Fasciitis	1	100.0%	0	0.0%	0	0.0%	1
Shoulder Blade Pain	2	100.0%	0	0.0%	0	0.0%	2
Shoulder Pain	5	55.6%	4	44.4%	0	0.0%	9
Spasms	5	83.3%	1	16.7%	0	0.0%	6
Thoracic Pain	0	0.0%	2	100.0%	0	0.0%	2
Trapezius Pain	1	100.0%	0	0.0%	0	0.0%	1
Tendonitis	0	0.0%	2	100.0%	0	0.0%	2
Other Musculoskeletal and Connective Tissue Disorder	1	100.0%	0	0.0%	0	0.0%	1
Nervous System Disorders	**29**	**70.7%**	**9**	**22.0%**	**3**	**7.3%**	**41**
Compressive neuropathy	3	100.0%	0	0.0%	0	0.0%	3
Headache	3	60.0%	2	40.0%	0	0.0%	5
Neurological deterioration (motor, sensory or reflex)	1	100.0%	0	0.0%	0	0.0%	1
Numbness/Tingling	1	100.0%	0	0.0%	0	0.0%	1
Numbness/Tingling, Upper Extremity	9	81.8%	2	18.2%	0	0.0%	11
Numbness/Tingling, Lower Extremity	1	100.0%	0	0.0%	0	0.0%	1
Numbness/Tingling, Oral	1	100.0%	0	0.0%	0	0.0%	1
Peripheral Neuropathy	0	0.0%	1	100.0%	0	0.0%	1
Radiculopathy (including radicular arm pain)	9	64.3%	2	14.3%	3	21.4%	14
Temporary or permanent nerve damage	0	0.0%	1	100.0%	0	0.0%	1
Weakness	1	50.0%	1	50.0%	0	0.0%	2
Psychiatric Disorders	**0**	**0.0%**	**4**	**100.0%**	**0**	**0.0%**	**4**
Anxiety Disorders	0	0.0%	1	100.0%	0	0.0%	1
Depression	0	0.0%	1	100.0%	0	0.0%	1
Insomnia	0	0.0%	1	100.0%	0	0.0%	1
Other Psychiatric Disorder	0	0.0%	1	100.0%	0	0.0%	1
Reproductive System and Breast Disorders	**1**	**50.0%**	**1**	**50.0%**	**0**	**0.0%**	**2**

	Mild		Moderate		Severe		Total
	Events	%*	Events	%*	Events	%*	Events
Other Reproductive System and Breast Disorder	1	50.0%	1	50.0%	0	0.0%	2
Skin and Subcutaneous Tissue Disorders	**2**	**50.0%**	**1**	**25.0%**	**1**	**25.0%**	**4**
Itching/Pruritus	2	100.0%	0	0.0%	0	0.0%	2
Wound complications (e.g., dehiscence, bruising) and soft tissue damage	0	0.0%	1	50.0%	1	50.0%	2
Vascular Disorders	**5**	**100.0%**	**0**	**0.0%**	**0**	**0.0%**	**5**
Angioedema	2	100.0%	0	0.0%	0	0.0%	2
Thromboembolic Event	1	100.0%	0	0.0%	0	0.0%	1
Hypertension	2	100.0%	0	0.0%	0	0.0%	2
Other Complications/Events	**3**	**50.0%**	**2**	**33.3%**	**1**	**16.7%**	**6**
Cancer	0	0.0%	0	0.0%	1	100.0%	1
Accident and injury	2	50.0%	2	50.0%	0	0.0%	4
Peripheral Swelling	1	100.0%	0	0.0%	0	0.0%	1
*Percentage of total events for that specific AE code. Row percentages will sum to 100%. Source: Tables Safety.sas; Analyzed: 19JUN2026							

Device-Related Adverse Events

Table 18 presents all device-related AEs recorded in the AT Analysis Set classified by the CEC as possibly, probably, or definitely related to the device. Overall, the investigational group presented with 15 device-related AEs in 6.3% (12/189) of the 189 BAGUERA® C subjects, compared to 10 device-related AEs in 9.4% (9/96) of the 96 Mobi-C subjects.

No device-related AE had a rate of 5% or more. The majority of device-related AEs occurred between Day 365 and Day 730 for the investigational group (n=6 AEs), and between Day 180 and Day 365 for the control group (n=4 AEs). Among device related AEs, there were 5 mild AEs, 5 moderate AEs, and 5 severe AEs reported in the BAGUERA® C group in the AT population (N=189). Among device related AEs l, there were 5 mild AEs, 2 moderate AEs, and 3 Severe AEs reported in the Mobi-C control group in the AT population (N=96).

Table 18 All Device-Related Adverse Events (AT Analysis Set, N=285)

	BAGUERA® C (N= 189)			Mobi-C (N= 96)			Diff.		
	Events	Subjs	%*	Events	Subjs	%*	%	LB†	UB†
All	**15**	**12**	**6.3%**	**10**	**9**	**9.4%**	**-3.0%**	**-9.8%**	**3.8%**
Device (non-system specific)	**0**	**0**	**0.0%**	**1**	**1**	**1.0%**	**-1.0%**		
Device Delivery System Malfunction	0	0	0.0%	1	1	1.0%	-1.0%		
Gastrointestinal Disorders	**0**	**0**	**0.0%**	**1**	**1**	**1.0%**	**-1.0%**		
Dysphagia	0	0	0.0%	1	1	1.0%	-1.0%		
Infections and Infestations	**1**	**1**	**0.5%**	**0**	**0**	**0.0%**	**0.5%**		
Infection, Surgical Site	1	1	0.5%	0	0	0.0%	0.5%		
Musculoskeletal and Connective Tissue Disorders	**7**	**6**	**3.2%**	**6**	**6**	**6.3%**	**-3.1%**	**-8.5%**	**2.4%**
Arm Pain (not radicular)	0	0	0.0%	2	2	2.1%	-2.1%		
Cervical pain (no narcotic given)	1	1	0.5%	2	2	2.1%	-1.6%		
Cervical pain (narcotic given)	1	1	0.5%	0	0	0.0%	0.5%		
Other Musculoskeletal Pain, Specify Location	2	2	1.1%	0	0	0.0%	1.1%		
Spasms	0	0	0.0%	1	1	1.0%	-1.0%		
Cervical Foraminal Stenosis	1	1	0.5%	0	0	0.0%	0.5%		
Muscle Weakness, Upper Extremity	1	1	0.5%	1	1	1.0%	-0.5%		
Shoulder Blade Pain	1	1	0.5%	0	0	0.0%	0.5%		
Nervous System Disorders	**7**	**6**	**3.2%**	**2**	**2**	**2.1%**	**1.1%**		
Headache	1	1	0.5%	0	0	0.0%	0.5%		
Radiculopathy (including radicular arm pain)	6	6	3.2%	1	1	1.0%	2.1%		
Numbness/Tingling, Upper Extremity	0	0	0.0%	1	1	1.0%	-1.0%		

*Percentage of subjects experiencing specific event.
† 95% Asymptotic CI reported when at least five subjects experienced the AE and at least five subjects did not experience the AE.
Source: Tables Safety.sas; Analyzed: 19JUN2026

Procedure-Related Adverse Events

Table 19 presents all procedure-related AEs recorded in the AT Analysis Set classified by the CEC as possibly, probably or definitely related to the study procedure. Overall, the investigational group presented with 53 procedure-related AEs in 21.2% (40/189) of the 189 BAGUERA® C subjects, compared to 26 procedure-related AEs in 20.8% (20/96) of the 96 Mobi-C subjects.

The most common procedure-related AEs included: dysphagia (investigational – 5.8%, 11/189; control – 8.3%, 8/96).

The majority of all procedure-related occurred between Day 2 and Day 30 for the investigational group (18 AEs), and between Day 0 and Day 2 for the control group (13 AEs). Among procedure-related AEs, there were 31 mild AEs, 18 moderate AEs, and 4 Severe AEs reported in the BAGUERA® C group in the AT population (N=189). Among procedure related AEs, there were 19 mild AEs, 3 moderate AEs, and 4 Severe AEs reported in the Mobi-C control group in the AT population (N=96).

Table 19 All Procedure-Related Adverse Events (AT Analysis Set, N=285)

	BAGUERA® C (N= 189)			Mobi-C (N= 96)			Diff.		
	Events	Subjs	%*	Events	Subjs	%*	%	LB†	UB†
All	**53**	**40**	**21.2%**	**26**	**20**	**20.8%**	**0.3%**	**-9.7%**	**10.3%**
Device (non system specific)	**0**	**0**	**0.0%**	**1**	**1**	**1.0%**	**-1.0%**		
Device Delivery System Malfunction	0	0	0.0%	1	1	1.0%	-1.0%		
Gastrointestinal Disorders	**12**	**12**	**6.3%**	**8**	**8**	**8.3%**	**-2.0%**	**-8.5%**	**4.5%**
Dysphagia	11	11	5.8%	8	8	8.3%	-2.5%	-9.0%	3.9%
Gastroesophageal Reflux Disease	1	1	0.5%	0	0	0.0%	0.5%		
Immune System Disorders	**1**	**1**	**0.5%**	**0**	**0**	**0.0%**	**0.5%**		
Foreign Body Reaction, Non-Implant	1	1	0.5%	0	0	0.0%	0.5%		
Infections and Infestations	**2**	**2**	**1.1%**	**0**	**0**	**0.0%**	**1.1%**		
Infection, Surgical Site	2	2	1.1%	0	0	0.0%	1.1%		
Musculoskeletal and Connective Tissue Disorders	**18**	**16**	**8.5%**	**11**	**10**	**10.4%**	**-2.0%**	**-9.2%**	**5.3%**
Arm Pain (not radicular)	1	1	0.5%	2	2	2.1%	-1.6%		
Cervical pain (no narcotic given)	4	4	2.1%	5	5	5.2%	-3.1%		
Cervical pain (narcotic given)	1	1	0.5%	0	0	0.0%	0.5%		
Other Musculoskeletal Pain, Specify Location	2	2	1.1%	0	0	0.0%	1.1%		
Spasms	4	4	2.1%	2	2	2.1%	0.0%		
Muscle Weakness, Upper Extremity	1	1	0.5%	1	1	1.0%	-0.5%		
Shoulder Blade Pain	2	2	1.1%	0	0	0.0%	1.1%		
Shoulder Pain	2	2	1.1%	1	1	1.0%	0.0%		
Trapezius Pain	1	1	0.5%	0	0	0.0%	0.5%		
Nervous System Disorders	**12**	**10**	**5.3%**	**4**	**4**	**4.2%**	**1.1%**		
Headache	2	2	1.1%	0	0	0.0%	1.1%		
Radiculopathy (including radicular arm pain)	7	7	3.7%	0	0	0.0%	3.7%		

	BAGUERA® C (N= 189)			Mobi-C (N= 96)			Diff.		
	Events	Subjs	%*	Events	Subjs	%*	%	LB†	UB†
Numbness/Tingling, Upper Extremity	2	2	1.1%	2	2	2.1%	-1.0%		
Numbness/Tingling, Oral	0	0	0.0%	1	1	1.0%	-1.0%		
Peripheral Neuropathy	1	1	0.5%	1	1	1.0%	-0.5%		
Respiratory, Thoracic and Mediastinal Disorders	**1**	**1**	**0.5%**	**0**	**0**	**0.0%**	**0.5%**		
Hemoptysis	1	1	0.5%	0	0	0.0%	0.5%		
Skin and Subcutaneous Tissue Disorders	**7**	**6**	**3.2%**	**2**	**2**	**2.1%**	**1.1%**		
Wound complications (e.g., dehiscence, bruising) and soft tissue damage.	7	6	3.2%	2	2	2.1%	1.1%		

*Percentage of subjects experiencing specific event.

† 95% Asymptotic CI reported when at least five subjects experienced the AE and at least five subjects did not experience the AE.
Source: Tables Safety.sas; Analyzed: 19JUN2026

Serious Adverse Events

Table 20 below presents a summary of all SAEs for all investigational BAGUERA® C subjects and Mobi-C control subjects in the AT analysis population (N=285). There were 71 SAEs in 27% (51/189) of the BAGUERA® C subjects and 28 SAEs in 24% (23/96) of the Mobi-C control group subjects as determined by the CEC. The most common SAE body system sub-category was radiculopathy in both the investigational group (6.3%; 12/189) and control group (4.2%; 4/96).

Table 20 Serious Adverse Events by AE Code – AT Analysis Set (N=285)

	BAGUERA® C (N= 189)			Mobi-C (N= 96)			Diff.		
	Events	Subjs	%*	Events	Subjs	%*	%	LB†	UB†
All	**71**	**51**	**27.0%**	**28**	**23**	**24.0%**	**3.0%**	**-7.6%**	**13.7%**
Cardiac Disorders	**1**	**1**	**0.5%**	**0**	**0**	**0.0%**	**0.5%**		
Other Cardiac Disorders	1	1	0.5%	0	0	0.0%	0.5%		
Eye Disorders	**0**	**0**	**0.0%**	**1**	**1**	**1.0%**	**-1.0%**		
Retinal Detachment	0	0	0.0%	1	1	1.0%	-1.0%		
Gastrointestinal Disorders	**0**	**0**	**0.0%**	**1**	**1**	**1.0%**	**-1.0%**		
Dysphagia	0	0	0.0%	1	1	1.0%	-1.0%		
General Disorders and Administrative Site Conditions	**1**	**1**	**0.5%**	**0**	**0**	**0.0%**	**0.5%**		
Hernia	1	1	0.5%	0	0	0.0%	0.5%		
Immune System Disorders	**1**	**1**	**0.5%**	**0**	**0**	**0.0%**	**0.5%**		
Foreign Body Reaction, Non-Implant	1	1	0.5%	0	0	0.0%	0.5%		
Infections and Infestations	**3**	**3**	**1.6%**	**1**	**1**	**1.0%**	**0.5%**		
Appendicitis	1	1	0.5%	0	0	0.0%	0.5%		
Infection, Surgical Site	1	1	0.5%	0	0	0.0%	0.5%		
Sinusitis	0	0	0.0%	1	1	1.0%	-1.0%		
Abscess, Oral	1	1	0.5%	0	0	0.0%	0.5%		
Musculoskeletal and Connective Tissue Disorders	**22**	**20**	**10.6%**	**13**	**13**	**13.5%**	**-3.0%**	**-11.1%**	**5.2%**
Arm Pain (not radicular)	0	0	0.0%	2	2	2.1%	-2.1%		
Cervical pain (no narcotic given)	0	0	0.0%	2	2	2.1%	-2.1%		
Joint pain	4	4	2.1%	2	2	2.1%	0.0%		
Cervical Foraminal Stenosis	3	3	1.6%	1	1	1.0%	0.5%		
Lumbar Spinal Stenosis	1	1	0.5%	1	1	1.0%	-0.5%		
Muscle Rupture	1	1	0.5%	3	3	3.1%	-2.6%		
Muscle Weakness, Upper Extremity	0	0	0.0%	1	1	1.0%	-1.0%		
Osteoarthritis	2	2	1.1%	0	0	0.0%	1.1%		
Plantar Fasciitis	1	1	0.5%	0	0	0.0%	0.5%		
Shoulder Pain	8	8	4.2%	1	1	1.0%	3.2%		
Trigger Finger	1	1	0.5%	0	0	0.0%	0.5%		
Fracture, Any Bone	1	1	0.5%	0	0	0.0%	0.5%		
Nervous System Disorders	**24**	**20**	**10.6%**	**8**	**6**	**6.3%**	**4.3%**	**-2.2%**	**10.9%**
Compressive neuropathy	8	7	3.7%	2	1	1.0%	2.7%		
Radiculopathy (including radicular arm pain)	13	12	6.3%	4	4	4.2%	2.2%		
Weakness	0	0	0.0%	1	1	1.0%	-1.0%		
Peripheral Neuropathy	2	2	1.1%	1	1	1.0%	0.0%		

	BAGUERA® C (N= 189)			Mobi-C (N= 96)			Diff.		
	Events	Subjs	%*	Events	Subjs	%*	%	LB†	UB†
Thoracic Outlet Syndrome	1	1	0.5%	0	0	0.0%	0.5%		
Psychiatric Disorders	**1**	**1**	**0.5%**	**0**	**0**	**0.0%**	**0.5%**		
Other Psychiatric Disorder	1	1	0.5%	0	0	0.0%	0.5%		
Renal and Urinary Disorders	**1**	**1**	**0.5%**	**0**	**0**	**0.0%**	**0.5%**		
Renal Calculi	1	1	0.5%	0	0	0.0%	0.5%		
Reproductive System and Breast Disorders	**9**	**7**	**3.7%**	**2**	**2**	**2.1%**	**1.6%**		
Polycystic Ovarian Syndrome	1	1	0.5%	0	0	0.0%	0.5%		
Uterine Neoplasm	4	4	2.1%	0	0	0.0%	2.1%		
Uterovaginal prolapse	1	1	0.5%	0	0	0.0%	0.5%		
Other Reproductive System and Breast Disorder	3	2	1.1%	2	2	2.1%	-1.0%		
Respiratory, Thoracic and Mediastinal Disorders	**1**	**1**	**0.5%**	**0**	**0**	**0.0%**	**0.5%**		
Hemoptysis	1	1	0.5%	0	0	0.0%	0.5%		
Skin and Subcutaneous Tissue Disorders	**0**	**0**	**0.0%**	**1**	**1**	**1.0%**	**-1.0%**		
Wound complications (e.g., dehiscence, bruising) and soft tissue damage	0	0	0.0%	1	1	1.0%	-1.0%		
Vascular Disorders	**1**	**1**	**0.5%**	**0**	**0**	**0.0%**	**0.5%**		
Other Vascular Disorder	1	1	0.5%	0	0	0.0%	0.5%		
Other Complications/Events	**6**	**5**	**2.6%**	**1**	**1**	**1.0%**	**1.6%**		
Cancer	2	2	1.1%	1	1	1.0%	0.0%		
Other Event, Describe	2	2	1.1%	0	0	0.0%	1.1%		
Accident and injury	2	1	0.5%	0	0	0.0%	0.5%		

*Percentage of subjects experiencing specific event.
† 95% Asymptotic CI reported when at least five subjects experienced the AE and at least five subjects did not experience the AE.
Source: Tables Safety.sas; Analyzed: 19JUN2026

Serious Adverse Events by Time course

Table 21 presents the SAEs through Month 24 for both treatment groups. The majority of SAEs occurred between Day 365 and Day 730 for the investigational group, and between Day 2 and Day 30 (6 SAEs) and Day 365 and Day 730 (6 SAEs) for the control group. While not shown, the majority of all device-related SAEs occurred between Day 365 and Day 730 (5 SAEs) for the investigational group, and between Day 180 and Day 365 (3 SAEs) for the control group.

Table 21 Serious Adverse Events (Time course) – AT Analysis Set, N=285

	Days Post-Op															
	<0		0-2		2-30		30-90		90-180		180-365		365-730		Total	
	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C
All	**0**	**0**	**3**	**1**	**3**	**6**	**11**	**6**	**14**	**3**	**10**	**6**	**30**	**6**	**71**	**28**
Cardiac Disorders	**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	1	0	0	0	1	0
Eye Disorders	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**1**
Retinal Detachment	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1
Gastrointestinal Disorders	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**0**	**0**	**1**
Dysphagia	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1
General Disorders and Administrative Site Conditions	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**1**	**0**
Hernia	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0
Immune System Disorders	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**0**	**0**	**0**	**0**	**1**	**0**
Foreign Body Reaction, Non-Implant	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1	0
Infections and Infestations	**0**	**0**	**0**	**0**	**1**	**0**	**0**	**1**	**1**	**0**	**0**	**0**	**1**	**0**	**3**	**1**
Appendicitis	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0
Infection, Surgical Site	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1	0
Sinusitis	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1
Abscess, Oral	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1	0
Musculoskeletal and Connective Tissue Disorders	**0**	**0**	**0**	**0**	**2**	**2**	**4**	**2**	**4**	**3**	**4**	**3**	**8**	**3**	**22**	**13**
Arm Pain (not radicular)	0	0	0	0	0	0	0	1	0	0	0	1	0	0	0	2
Cervical pain (no narcotic given)	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0	2
Joint pain	0	0	0	0	0	0	0	0	2	2	1	0	1	0	4	2
Cervical Foraminal Stenosis	0	0	0	0	1	0	0	0	0	1	1	0	1	0	3	1
Lumbar Spinal Stenosis	0	0	0	0	0	1	1	0	0	0	0	0	0	0	1	1
Muscle Rupture	0	0	0	0	0	0	0	1	0	0	1	1	0	1	1	3
Muscle Weakness, Upper Extremity	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1
Osteoarthritis	0	0	0	0	0	0	0	0	1	0	0	0	1	0	2	0
Plantar Fasciitis	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1	0
Shoulder Pain	0	0	0	0	0	0	3	0	0	0	1	0	4	1	8	1
Trigger Finger	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0
Fracture, Any Bone	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1	0
Nervous System Disorders	**0**	**0**	**2**	**0**	**0**	**3**	**6**	**3**	**5**	**0**	**3**	**2**	**8**	**0**	**24**	**8**
Compressive neuropathy	0	0	1	0	0	2	0	0	4	0	1	0	2	0	8	2
Radiculopathy (including radicular arm pain)	0	0	0	0	0	0	4	2	1	0	2	2	6	0	13	4
Weakness	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1
Peripheral Neuropathy	0	0	1	0	0	1	1	0	0	0	0	0	0	0	2	1

	Days Post-Op															
	<0		0-2		2-30		30-90		90-180		180-365		365-730		Total	
	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C
Thoracic Outlet Syndrome	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	0
Psychiatric Disorders	**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	1	0	0	0	0	0	1	0
Renal and Urinary Disorders	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**1**	**0**
Renal Calculi	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0
Reproductive System and Breast Disorders	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**2**	**0**	**1**	**0**	**5**	**2**	**9**	**2**
Polycystic Ovarian Syndrome	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	0
Uterine Neoplasm	0	0	0	0	0	0	0	0	2	0	1	0	1	0	4	0
Uterovaginal prolapse	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0
Other Reproductive System and Breast Disorder	0	0	0	0	0	0	0	0	0	0	0	0	3	2	3	2
Respiratory, Thoracic and Mediastinal Disorders	**0**	**0**	**1**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**0**
Hemoptysis	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1	0
Skin and Subcutaneous Tissue Disorders	**0**	**0**	**0**	**1**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**1**
Wound complications (e.g., dehiscence, bruising) and soft tissue damage	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1
Vascular Disorders	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**0**	**0**	**1**	**0**
Other Vascular Disorder	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0
Other Complications/Events	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**0**	**0**	**0**	**0**	**0**	**6**	**0**	**6**	**1**
Cancer	0	0	0	0	0	1	0	0	0	0	0	0	2	0	2	1
Other Event, Describe	0	0	0	0	0	0	0	0	0	0	0	0	2	0	2	0
Accident and injury	0	0	0	0	0	0	0	0	0	0	0	0	2	0	2	0

Source: Tables Safety.sas; Analyzed: 19JUN2026

Secondary Surgical Interventions

Some AEs resulted in Secondary Surgical Interventions (SSIs) that were prospectively classified as revisions, removals, reoperations or supplemental fixations, qualified as study failures in accordance with FDA's Guidance Document, Clinical Data Presentations for Orthopedic Device Applications (2004) and were reviewed and adjudicated by the CEC.

Based on the results presented in Table 22, a total of nine (9) SSIs occurred in the investigational group, and three (3) SSIs occurred in the control group. Of the investigational group SSIs, one (1) occurred on post-operative day 935 (post 2-year anniversary) and one (1) occurred on post-operative day 805 and are therefore not included in the subject accounting table and overall success table.

The time course of these events demonstrates that the majority of SSIs occurred between 12 and 24 months in both groups; however, meaningful conclusions cannot be made with respect to timing due to the low number of SSI events in both groups.

Table 22 SSI Time course by Treatment Type – AT Analysis Set, N = 285

Treatment Group	Event Time-Course (months)						Total Subjects
	SSI Type	< 1.5	1.5-3	3-6	6-12	12-24	
BAGUERA C	Removal	-	-	-	2	2	4
	Revision	-	-	-	-	-	-
	Reoperation	-	-	-	2	1*	3
	Supplemental Fixation	-	-	-	-	2*	2
Total Events (subjects)		**-**	**-**	**-**	**4**	**5**	**9**
Mobi-C (Control)	Removal	-	-	-	1	-	1
	Revision	-	-	-	-	-	-
	Reoperation	-	-	-	2	-	2
	Supplemental Fixation	-	-	-	-	-	-
Total Events (subjects)		**-**	**-**	**-**	**3**	**-**	**3**

Two SSIs occurred on day 805 and day 935 post-operative and are therefore not included in the survival analysis, subject accounting table and overall success table.

The procedure and reason for SSI are detailed below in Table 23. Of the nine (9) SSIs observed in the BAGUERA® C investigational group, four (4) resulted in device removal. Of the three (3) SSIs reported in the Mobi-C control cohort, one (1) resulted in device removal.

Table 23 Surgical Intervention Procedure and Indication for Procedure

Group	Procedure	Index Level	Procedure	Indication for Procedure
BAGUERA® C	Reoperation	C6-C7	C5-C7 foraminotomy	Severe foraminal stenosis at C5-C6 and index level (C6-C7
BAGUERA® C	Removal	C6-C7	Explant of the BAGUERA® C device and subsequent single-level ACDF performed at C6-C7	Diminished sensation at left C8, foraminal stenosis from C1-C7
BAGUERA® C	Removal	C6-C7	Explant of the BAGUERA® C device at C6-C7 and subsequent ACDF at C4-C7 with C5 corpectomy	Osteomyelitis/discitis at C4-C6
BAGUERA® C	Reoperation	C5-C6	Posterior decompression at C5-C6	Decreased sensation to left C6-C8. C5-C6 foraminal stenosis.
BAGUERA® C	Removal	C5-C6	Explant of the BAGUERA® C device, C5-C6 decompression and ACDF at C5-C6	Diminished left C6-7 sensation. Increased balance changes due to worsening of pre-existing cervical myelopathy (due to foraminal stenosis at C5-C6)
BAGUERA® C	Supplemental Fixation	C5-C6	Posterior fusion at C3-C6 with total facetectomy at C5-C6.	C5-C6 right foraminal collapse
BAGUERA® C	Supplemental Fixation	C5-C6	Posterior cervical fusion and cervical laminectomy at C5-C7	Recurrent cervical radiculopathy
BAGUERA® C	Removal	C6-C7	Explant of the BAGUERA® C device and ACDF at C6-C7	Midline C6-C7 tenderness with neck pain that radiated to both arms
BAGUERA® C	Reoperation	C4-C5	Lamino-foraminotomy with resection of a synovial cyst	Radiculopathy
Mobi-C	Reoperation	C6-C7	Posterior cervical laminectomy and posterior lamino-foraminotomy at C5-C7	Foraminal stenosis at multiple levels
Mobi-C	Removal	C5-C6	Explant of the Mobi-C device and ACDF at C5-C6	Device migration
Mobi-C	Reoperation	C5-C6	Foraminotomy at C5-C6	Foraminal stenosis at C5-C6

Neurological Status

The following tables specify the number and percentage of subjects who improved, maintained, or deteriorated in neurological status at each protocol-required follow-up. At 24 months, 95.0% of BAGUERA® C subjects and 96.4% of Mobi-C subjects experienced maintenance or improvement in sensory status relative to baseline (Table 24).

Table 24 Change in Neurological Sensory Status at Month 12 and Month 24 (Primary Analysis Population)

	Month 12						Month 24					
	I			C			I			C		
Sensory Status	**n**	**N**	**%**	**n**	**N**	**%**	**n**	**N**	**%**	**n**	**N**	**%**
Deteriorated	6	181	3.3%	0	92	0.0%	9	177	5.1%	3	84	3.6%
Maintained	71	181	39.2%	42	92	45.7%	67	177	37.9%	37	84	44.0%
Improved	104	181	57.5%	50	92	54.3%	101	177	57.1%	44	84	52.4%
Source: Tables Neuro Status.sas; Analyzed: 13JUL2026												

At 24 months 98.3% of BAGUERA C and 97.6% on Mobi-C Subjects maintained or improved in reflex status relative to baseline (Table 25).

Table 25 Change in Neurological Reflex Status at Month 12 and Month 24 (Primary Analysis Population)

	Month 12						Month 24					
	I			C			I			C		
Reflex Status	**n**	**N**	**%**	**n**	**N**	**%**	**n**	**N**	**%**	**n**	**N**	**%**
Deteriorated	3	181	1.7%	0	92	0.0%	3	177	1.7%	2	84	2.4%
Maintained	125	181	69.1%	65	92	70.7%	122	177	68.9%	57	84	67.9%
Improved	53	181	29.3%	27	92	29.3%	52	177	29.4%	25	84	29.8%
Source: Tables Neuro Status.sas; Analyzed: 13JUL2026												

At 24 months, 100% of BAGUERA C and 100% of Mobi-C subjects maintained or improved in motor status relative to baseline (Table 26).

Table 26 Change in Neurological Motor Status at Month 12 and Month 24 (Primary Analysis Population)

	Month 12						Month 24					
	I			C			I			C		
Motor Status	**n**	**N**	**%**	**n**	**N**	**%**	**n**	**N**	**%**	**n**	**N**	**%**
Deteriorated	0	181	0.0%	0	92	0.0%	0	177	0.0%	0	84	0.0%
Maintained	164	181	90.6%	76	92	82.6%	161	177	91.0%	69	84	82.1%
Improved	17	181	9.4%	16	92	17.4%	16	177	9.0%	15	84	17.9%
Source: Tables Neuro Status.sas; Analyzed: 13JUL2026												

Neurological success was defined as maintenance or improvement in neurologic status at Month 24. The CEC reviewed investigator assigned neurologic status at Month 24 as compared to baseline for all subjects demonstrated a negative change in neurologic status to determine if the

change was clinical relevant to the index level. At Month 24, four (4) BAGUERA® C subjects were considered a neurological failure (2.1% - 4/189) and one (1) Mobi-C control subjects was considered neurological failure (1.0% - 1/96).

b) Effectiveness Results

The analysis of effectiveness was based on 285 subjects (189 investigational; 96 control) evaluable for primary CCS at Month 24. Key effectiveness outcomes are presented in Table 27.

This clinical trial was designed to test the non-inferiority of the investigational device (BAGUERA® C Cervical Disc Prosthesis) as compared to the control device (Mobi-C) when used at a single-level in the spine through the use of a primary composite endpoint.

Overall Success

A subject was considered a study success at the Month 24 if he/she met all of the following criteria:

1. Improvement in pain and function, as measured through the Neck Disability Index (NDI), of at least 15 percentage points (out of 100%) from pre-operative;
2. Maintenance or improvement in neurological status at 24 months compared to baseline (as determined by the CEC)
3. No secondary surgical intervention defined as revision, removal, reoperation, or supplemental fixation at the index level
4. No serious adverse event(s) confirmed as device or procedure related (as determined by the CEC).

Overall success was determined based on the PP Analysis Set at Month 24. The primary overall success outcomes are presented in Table 27.

Table 27 Overall Success (PP Analysis Set, N=285)

Month 24 Overall Efficacy - One Level (PP) Analysis Set (N = 285)											
	BAGUERA® C			**MOBI-C**			**Group Difference**				
	N	**n**	**%**	**N**	**n**	**%**	**Δ[1]**	**LB[2]**	**UB[2]**		
[1] No Secondary Surgical Intervention	189	182	96.3%	96	93	96.9%	-0.6%	-5.1%	5.5%		
[2] No Serious Adverse Events (CEC)	189	187	98.9%	96	93	96.9%	2.1%	-1.5%	8.0%		
[3] NDI 15-Point Responder	177	163	92.1%	84	79	94.0%	-2.0%	-8.2%	6.2%		
[4] No Neurological Deterioration (CEC)	177	174	98.3%	84	84	>99.9	-1.7%	-5.0%	3.0%		
Composite Clinical Success							Δ[3]	LB[4]	UB[4]	PostProb NI[5]	PredProb NI[6]
[5] CCS with Bayesian Imputation	189	-	89.0%	96	-	89.8%	-0.8%	-7.9%	7.0%	>99.9	>99.9
Sensitivity Analysis 1							Δ[3]	LB[4]	UB[4]	PostProb NI[5]	
[6] CCS Complete Case Analysis	181	161	89.0%	85	76	89.4%	0.0%	-7.6%	8.6%	>99.9	
Sensitivity Analysis 2							Δ	LB	UB	1-Sided LB[7]	
[7] CCS Frequentist Imputation Analysis	189	-	89.1%	96	-	89.9%	-0.9%	-8.7%	7.0%	-7.5%	

[1]Difference in binomial proportions.
[2]Exact 95% CI for difference of proportions.
[3]Difference in mean of beta posteriors.
[4]Quantile based 95% posterior credible interval.
[5]Posterior Probability of Non-Inferiority
[6]Predictive Probability of Non-Inferiority (NI) (δ = -12.5%).
[7]1-Sided 95% Confidence Interval Lower Bound
All Bayesian distributions calculated from Beta(1,1) prior.
Results derived from 50000 separate sets of imputations with 10000 samples drawn for calculation of posterior probabilities. Posterior credible intervals estimated using 50000 samples.
Source: Tables Bayesian Interim.R; Analyzed: June 29, 2026

The imputed success rate for the investigational group was 89.0% as compared to an imputed success rate of 89.8% for the control group (difference -0.8% and 95% Bayesian Credible Interval for the difference [-7.9%,

7.0%]. Posterior probability is shown to demonstrate that non-inferiority has been achieved. In this study, the posterior probability of greater than 99.9% indicates there is greater than 99.9% 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 95% to declare success, which was achieved in this analysis.

A secondary supporting sensitivity analysis of the primary endpoint was performed with no imputation on the mITT analysis set. The results were similar, with a success rate of 89.0% (161/181) as compared to a success rate of 89.4% (76/85) for the control group. Non-inferiority was also demonstrated in this secondary analysis.

Composite Clinical Success Subcomponents

In looking at the individual subcomponents of the CCS in Table 27, the results are similar between both treatment groups. Row [1] identifies that 96.3% (182/189) of the investigational subjects and 96.9% (93/96) of the control subjects did not experience an SSI. Row [2] identifies that 98.9% (187/189) of the investigational subjects and 96.9% (93/96) of the control subjects did not experience a serious AE definitely related to the device or procedure. Row [3] indicates that 92.1% (163/177) of the investigational subjects and 94% (79/84) 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 98.3% (174/177) of the investigational subjects and >99.9% (84/84) of the control subjects did not experience neurological deterioration.

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 as discussed in Section X.A.1.d.

Neck Disability Index (NDI)

Table 28 shows the mean NDI score for the mITT Analysis Set over time through Month 24. In the investigational group, the mean NDI score decreased from 57.4 at screening to 13.9 at Month 24. In the control group, the mean NDI score decreased from 54.9 at screening to 10.0 at Month 24.

Table 28 NDI score values over time (mITT Analysis Set, N=285)

	BAGUERA® C						Control						Group Difference	
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	Diff.	p*
Screening	189	57.4	15.9	56.0	30.0	96.0	96	54.9	13.9	55.0	30.0	88.0	2.6	0.101
Week 06	188	22.4	18.6	18.0	0.0	94.0	95	19.0	15.1	18.0	0.0	86.0	3.4	0.157
Month 03	184	15.3	16.7	10.0	0.0	78.0	93	13.2	14.3	10.0	0.0	82.0	2.1	0.376
Month 06	187	12.6	15.8	6.0	0.0	70.0	94	12.6	14.9	8.0	0.0	86.0	0.1	0.216
Month 12	181	11.8	15.0	6.0	0.0	64.0	91	10.4	13.3	6.0	0.0	64.0	1.4	0.483
Month 24	177	13.9	17.4	6.0	0.0	80.0	84	10.0	14.5	4.0	0.0	66.0	3.8	0.076

*Two-sided 95% Wilcoxon Rank Sum test.
Source: Tables Clinical Follow-up.sas; Analyzed: 19JUN2026

Table 29 presents the number and percentage of subjects showing an improvement in NDI score greater than 15 percentage points as compared to all subjects in the study at each follow up time point for both the investigational and control groups. At Month 24, 92.1% (163/177) of

investigational subjects achieved greater than a 15-percentage point improvement in NDI score as compared to baseline, while 94.0% (79/84) of control subjects achieved greater than a 15-percentage point improvement in NDI score as compared to baseline.

Table 29 NDI 15-Percentage Point Responder (mITT Analysis Set, N=285)

	BAGUERA® C			Control			Group Difference*			
	N	n	%	N	n	%	Δ	LB	UB	p
Week 06	188	153	81.4%	95	82	86.3%	-4.9%	-13.8%	3.9%	0.296
Month 03	184	170	92.4%	93	86	92.5%	-0.1%	-6.7%	6.5%	0.981
Month 06	187	173	92.5%	94	90	95.7%	-3.2%	-8.8%	2.3%	0.297
Month 12	181	174	96.1%	91	87	95.6%	0.5%	-4.5%	5.6%	0.835
Month 24	177	163	92.1%	84	79	94.0%	-2.0%	-8.4%	4.5%	0.570

*Device group differences, Nominal 95% CI, and two-sided asymptotic p-value.
Source: Tables Clinical Follow-up. sas; Analyzed: 19JUN2026

Neck Pain – VAS

Table 30 reports the mean VAS – Neck Pain score for the mITT Analysis Set over time through Month 24. In the investigational group, the mean VAS – Neck Pain score decreased from 73.6 at screening to 16.2 at Month 24. In the control group, the mean VAS – Neck Pain score decreased from 74.3 at screening to 13.9 at Month 24.

Table 30 VAS Pain (Neck) values over time (mITT Analysis Set, N=285)

	BAGUERA® C						Control						Group Difference	
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	Diff.	p*
Screening	189	73.6	19.7	75.0	3.0	100.0	96	74.3	20.6	77.5	0.0	100.0	-0.7	0.253
Week 06	188	21.2	24.0	12.0	0.0	94.0	95	18.9	21.1	13.0	0.0	100.0	2.2	0.343
Month 03	184	16.0	22.7	5.0	0.0	97.0	93	13.4	18.6	6.0	0.0	77.0	2.7	0.464
Month 06	187	14.6	22.3	5.0	0.0	100.0	94	14.6	23.1	3.5	0.0	80.0	0.0	0.431
Month 12	181	13.4	20.2	4.0	0.0	84.0	91	12.5	21.1	4.0	0.0	86.0	0.9	0.396
Month 24	176	16.2	24.3	3.0	0.0	100.0	84	13.9	23.5	1.0	0.0	82.0	2.3	0.170

*Two-sided 95% Wilcoxon Rank Sum test.
Source: Tables Clinical Follow-up.sas; Analyzed: 19JUN2026

Table 31 presents the number and percentage of subjects showing an improvement in VAS – Neck Pain score greater than 20 points as compared to all subjects in the study at each follow up time point for both the investigational and control groups. At Month 24, 87.0% (147/169) of investigational subjects achieved greater than a 20-point improvement in VAS – Neck Pain score as compared to baseline, while 88.9% (72/81) of

control subjects achieved greater than a 20 point improvement in VAS – Neck pain score as compared to baseline.

Table 31 VAS Pain (Neck) Responder (mITT Analysis Set, N=285)

	BAGUERA® C			Control			Group Difference*			
	N	n	%	N	n	%	Δ	LB	UB	p
Week 06	181	157	86.7%	91	81	89.0%	-2.3%	-10.4%	5.8%	0.593
Month 03	178	161	90.4%	90	82	91.1%	-0.7%	-8.0%	6.6%	0.860
Month 06	180	162	90.0%	91	82	90.1%	-0.1%	-7.6%	7.4%	0.977
Month 12	175	165	94.3%	87	80	92.0%	2.3%	-4.3%	9.0%	0.471
Month 24	169	147	87.0%	81	72	88.9%	-1.9%	-10.4%	6.6%	0.669

*Device group differences, Nominal 95% CI, and two-sided asymptotic p-value.
Restricted to subjects with baseline VAS Neck of 20 points or greater.
Source: Tables Clinical Follow-up.sas; Analyzed: 19JUN2026

Right Shoulder/Arm Pain – VAS

Table 32 describes the mean VAS – Right Shoulder/Arm Pain score for the mITT Analysis Set over time through Month 24. In the investigational group, the mean VAS – Right Shoulder/Arm Pain score decreased from 44.9 at screening to 10.3 at Month 24. In the control group, the mean VAS– Right Shoulder/Arm Pain score decreased from 44.1 at screening to 6.0 at Month 24.

Table 32 VAS Pain (Right Shoulder/Arm) values over time (mITT Analysis Set, N=285)

	BAGUERA® C						Control						Group Difference	
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	Diff.	p*
Screening	189	44.9	36.4	53.0	0.0	100.0	96	44.1	37.6	48.0	0.0	100.0	0.7	0.419
Week 06	188	14.6	21.6	4.0	0.0	92.0	95	10.9	20.3	1.0	0.0	86.0	3.8	0.074
Month 03	184	9.9	17.7	0.5	0.0	97.0	93	7.3	16.7	0.0	0.0	80.0	2.6	0.101
Month 06	187	10.5	20.8	0.0	0.0	94.0	94	7.4	18.2	0.0	0.0	91.0	3.1	0.069
Month 12	181	8.4	16.4	0.0	0.0	75.0	91	7.9	16.4	0.0	0.0	85.0	0.6	0.360
Month 24	176	10.3	20.6	0.0	0.0	100.0	84	6.0	16.4	0.0	0.0	80.0	4.3	0.064

*Two-sided 95% Wilcoxon Rank Sum test.
Source: Tables Clinical Follow-up.sas; Analyzed: 19JUN2026

Table 33 identifies the number and percentage of subjects showing an improvement in VAS – Right Shoulder/Arm Pain score greater than 20 points as compared to all subjects in the study at each follow up time point for both the investigational and control groups. At Month 24, 90.0% (99/110) of investigational subjects achieved greater than a 20-point improvement in VAS – Right Shoulder/Arm Pain score as compared to baseline, while 93.6% (44/47) of control subjects achieved greater than a

20-point improvement in VAS – Right Shoulder/Arm Pain score as compared to baseline.

Table 33 VAS Right Shoulder/Arm Pain 20-Point Responder (mITT Analysis Set, N=285)

	BAGUERA® C			Control			Group Difference*			
	N	n	%	N	n	%	Δ	LB	UB	p
Week 06	118	104	88.1%	55	50	90.9%	-2.8%	-12.4%	6.8%	0.587
Month 03	114	108	94.7%	52	50	96.2%	-1.4%	-8.1%	5.2%	0.693
Month 06	117	105	89.7%	53	50	94.3%	-4.6%	-12.9%	3.7%	0.328
Month 12	113	108	95.6%	52	50	96.2%	-0.6%	-7.0%	5.9%	0.864
Month 24	110	99	90.0%	47	44	93.6%	-3.6%	-12.6%	5.3%	0.466

*Device group differences, Nominal 95% CI, and two-sided asymptotic p-value.
Restricted to subjects with baseline VAS Right Arm of 20 points or greater.
Source: Tables Clinical Follow-up.sas; Analyzed: 19JUN2026

Left Shoulder/Arm Pain – VAS

Table 34 describes the mean VAS – Left Shoulder/Arm Pain score for the mITT Analysis Set over time through Month 24. In the investigational group, the mean VAS – Left Shoulder/Arm Pain score decreased from 51.9 at screening to 9.9 at Month 24. In the control group, the mean VAS– Left Shoulder/Arm Pain score decreased from 52.4 at screening to 6.0 at Month 24.

Table 34 VAS Pain (Left Shoulder/Arm) values over time (mITT Analysis Set, N=285)

	BAGUERA® C						Control						Group Difference	
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	Diff.	p*
Screening	189	51.9	36.1	66.0	0.0	100.0	96	52.4	34.5	61.0	0.0	100.0	-0.5	0.471
Week 06	188	14.1	22.4	3.0	0.0	94.0	95	11.4	18.7	2.0	0.0	100.0	2.7	0.232
Month 03	184	12.1	22.2	1.0	0.0	100.0	93	5.6	11.6	0.0	0.0	53.0	6.5	0.031
Month 06	187	9.5	21.0	0.0	0.0	100.0	94	9.3	19.8	0.0	0.0	77.0	0.2	0.342
Month 12	181	7.9	18.0	0.0	0.0	100.0	91	6.6	15.6	0.0	0.0	90.0	1.3	0.245
Month 24	176	9.9	20.9	0.0	0.0	97.0	84	6.0	13.5	0.0	0.0	63.0	4.0	0.156

*Two-sided 95% Wilcoxon Rank Sum test.
Source: Tables Clinical Follow-up.sas; Analyzed: 19JUN2026

Table 35 identifies the number and percentage of subjects showing an improvement in VAS – Left Shoulder/Arm Pain score greater than 20 points as compared to all subjects in the study at each follow up time point for both the investigational and control groups. At Month 24, 91.1% (113/124) of investigational subjects achieved greater than a 20-point improvement in VAS – Left Shoulder/Arm Pain score as compared to baseline, while 98.4%

(61/62) of control subjects achieved greater than a 20-point improvement in VAS – Left Shoulder/Arm Pain score as compared to baseline.

Table 35 VAS Left Shoulder/Arm Pain 20-Point Responder (mITT Analysis Set, N=285)

	BAGUERA® C			Control			Group Difference*			
	N	n	%	N	n	%	Δ	LB	UB	p
Week 06	133	114	85.7%	68	63	92.6%	-6.9%	-15.5%	1.7%	0.152
Month 03	131	119	90.8%	69	68	98.6%	-7.7%	-13.4%	-2.0%	0.035
Month 06	132	119	90.2%	69	64	92.8%	-2.6%	-10.6%	5.4%	0.540
Month 12	127	117	92.1%	65	62	95.4%	-3.3%	-10.2%	3.7%	0.395
Month 24	124	113	91.1%	62	61	98.4%	-7.3%	-13.2%	-1.4%	0.058

*Device group differences, Nominal 95% CI, and two-sided asymptotic p-value.
Restricted to subjects with baseline VAS Left Arm of 20 points or greater.
Source: Tables Clinical Follow-up.sas; Analyzed: 19JUN2026

Dysphagia Handicap Index

DHI was administered to subjects in order to assess swallowing difficulties. As Table 36 reports, in the investigational group, the pre-operative DHI mean score was 6.6, minimally increased to 7.1 at Week 6 and dropped post-operatively to a Month 24 DHI mean score of 3.5. Similarly, in the control group, the pre-operative DHI mean score was 5.5, minimally increased to 5.7 at Week 6 and also dropped post-operatively to a Month 24 DHI mean score of 1.9. This suggests that as a whole, both the investigational and control treatments do not significantly contribute to development of swallowing difficulties.

Table 36 DHI Scores Over Time (mITT Analysis Set, N=285)

	BAGUERA® C						Control						Group Difference	
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	Dif	p*
Screening	188	6.6	10.9	2.0	0.0	64.0	96	5.5	10.5	2.0	0.0	54.0	1.1	0.105
Week 06	188	7.1	13.2	2.0	0.0	90.0	94	5.7	10.0	2.0	0.0	50.0	1.5	0.377
Month 03	184	4.0	9.8	0.0	0.0	78.0	93	3.4	7.7	0.0	0.0	60.0	0.6	0.156
Month 06	187	3.9	9.8	0.0	0.0	72.0	94	3.1	8.1	0.0	0.0	52.0	0.8	0.441
Month 12	179	3.9	10.3	0.0	0.0	60.0	91	1.6	3.1	0.0	0.0	14.0	2.3	0.367
Month 24	177	3.5	9.3	0.0	0.0	68.0	83	1.9	3.7	0.0	0.0	18.0	1.7	0.237

*Two-sided 95% Wilcoxon Rank Sum test.
Source: Tables Clinical Follow-up.sas; Analyzed: 19JUN2026

Short Form (SF-12v2) Physical Component Scores (PCS)

The results of the PCS portion of the SF-12v2 are shown in Table 37**.** In the investigational group, the pre-operative SF-12v2 PCS mean score was 34.7,

and increased post-operatively to a Month 24 SF-12v2 PCS mean score of 47.5. Similarly, in the control group, the pre-operative SF-12v2 PCS mean score was 34.8, and also increased post-operatively to a Month 24 SF-12v2 PCS mean score of 47.9.

Table 37 SF-12 (PCS) values over time (mITT Analysis Set, N=285)

	BAGUERA® C						Control						Group Difference	
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	Dif	p*
Screening	189	34.7	7.0	34.8	13.8	51.8	96	34.8	6.7	34.8	18.6	53.6	-0.1	0.488
Month 06	186	47.7	6.5	48.7	24.1	65.0	93	47.6	6.9	48.7	23.7	62.2	0.1	0.366
Month 12	181	47.7	6.3	48.7	21.6	59.0	90	48.7	6.6	49.0	23.9	63.2	-1.0	0.080
Month 24	177	47.5	6.3	48.7	26.9	59.3	84	47.9	7.3	49.9	21.9	61.2	-0.4	0.089

*Two-sided 95% Wilcoxon Rank Sum test.
Source: Tables Clinical Follow-up.sas; Analyzed: 19JUN2026

Short Form (SF-12v2) Mental Component Scores (MCS)

The results of the MCS portion of the SF-12v2 are shown in Table 38**.** In the investigational group, the pre-operative SF-12v2 MCS mean score was 45.6, and increased post-operatively to a Month 24 SF-12v2 MCS mean score of 53.4. Similarly, in the control group, the pre-operative SF-12v2 MCS mean score was 45.8, and also increased post-operatively to a Month 24 SF-12v2 MCS mean score of 54.6.

Table 38 SF-12 (MCS) values over time (mITT Analysis Set, N=285)

	BAGUERA® C						Control						Group Difference	
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	Dif	p*
Screening	189	45.6	11.5	45.8	18.2	67.1	96	45.8	11.7	47.0	18.6	66.7	-0.2	0.425
Month 06	186	52.9	8.6	55.1	24.7	65.8	93	54.0	8.2	55.5	18.1	65.8	-1.1	0.213
Month 12	181	53.0	8.9	55.2	25.1	69.7	90	53.9	8.6	57.0	19.9	65.8	-0.9	0.225
Month 24	177	53.4	8.4	56.3	18.9	64.8	84	54.6	8.3	57.5	21.7	69.7	-1.2	0.198

*Two-sided 95% Wilcoxon Rank Sum test.
Source: Tables Clinical Follow-up.sas; Analyzed: 19JUN2026

Odom's Criteria

Odom's Criteria consist of a 4-point rating scale for surgeons to assess clinical outcomes following cervical spine surgery. Table 39 provides the ratings for Odom's Criteria in the clinical study. In both groups, the predominant response is "Excellent" or "Good" at Month 24 timepoint. At Month 24, a response of "Excellent" or "Good" was reported in 96.6%

(171/177) of investigational cases, and similarly, a response of "Excellent" or "Good" was reported in 96.4% (81/84) of control cases.

Table 39 Odom's Criteria (mITT Analysis Set, N=285)

	Month 24			
	BAGUERA® C		Control	
	n	%	n	%
Excellent	135	76%	69	82%
Good	36	20%	12	14%
Fair	4	2%	1	1%
Poor	2	1%	2	2%
Subjects censored at Index level secondary surgical interventions. Source: Tables Clinical Follow-up.sas; Analyzed: 19JUN2026				

Patient Satisfaction

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

Table 40 presents the subject responses for both the BAGUERA® C investigational group and the Mobi-C control group to the survey question, "How satisfied are you with the overall result of your surgery?". The response options included "Very Satisfied", "Somewhat Satisfied", "Neither Satisfied nor Dissatisfied", "Somewhat Dissatisfied" and "Very Dissatisfied". A total 80.2% (142/177) of investigational subjects reported that they were "Very Satisfied" at Month 24, as compared to a total of 88.1% (74/84) of control subjects expressing this perspective at Month 24. 5.1% (9/177) of subjects in the investigational group reported being "Somewhat Dissatisfied" or "Very Dissatisfied" at Month 24 as compared to 4.8% (4/84) of control subjects.

Table 40 Treatment Satisfaction:
"How Satisfied are you with the overall result of your surgery?"
(mITT Analysis Set, N=285)

	Month 12				Month 24			
	BAGUERA® C		Control		BAGUERA® C		Control	
	n	%	n	%	n	%	n	%
Very Satisfied	157	87%	81	89%	142	80%	74	88%
Somewhat Satisfied	11	6%	8	9%	19	11%	5	6%
Neither Satisfied nor Dissatisfied	6	3%	0	0%	7	4%	1	1%
Somewhat Dissatisfied	4	2%	2	2%	7	4%	2	2%
Very Dissatisfied	3	2%	0	0%	2	1%	2	2%
Source: Tables Clinical Follow-up.sas; Analyzed: 19JUN2026								

Table 41 presents the subject responses to the survey question, "All things considered, would you have the surgery again?". The response options included "Definitely", "Probably", "Possibly", "Probably Not" and "Definitely Not". A total 81.9% (145/177) of investigational subjects answered "Definitely" at Month 24, as compared to a total of 86.9% (73/84) of control subjects expressing this perspective at Month 24. 4.5% (8/177) of subjects in the investigational group answered "Probably Not" or "Definitely Not" at Month 24 as compared to 2.4% (2/84) of control subjects.

Table 41 Treatment Satisfaction: "All things considered, would you have the surgery again?" (mITT Analysis Set, N=285)

	Month 12				Month 24			
	BAGUERA® C		Control		BAGUERA® C		Control	
	n	%	n	%	n	%	n	%
Definitely	146	81%	83	91%	145	82%	73	87%
Probably	22	12%	5	5%	17	10%	8	10%
Possibly	7	4%	3	3%	7	4%	1	1%
Probably Not	5	3%	0	0%	6	3%	1	1%
Definitely Not	1	1%	0	0%	2	1%	1	1%
Source: Tables Clinical Follow-up.sas; Analyzed: 19JUN2026								

Table 42 presents the subject responses to the survey question, "Would you recommend the surgery to a friend or family member?". The response options included "Definitely", "Probably", "Possibly", "Probably Not" and "Definitely Not". A total 82.5% (146/177) of investigational subjects answered "Definitely" at Month 24, as compared to a total of 89.3% (75/84) of control subjects expressing this perspective at Month 24. 4.0% (7/177) of subjects in the investigational group answered "Probably Not" or "Definitely Not" at Month 24 as compared to 2.4% (2/84) of control subjects.

Table 42 Treatment Satisfaction: "Would you recommend the surgery to a friend or family member?" (mITT Analysis Set, N=285)

	Month 12				Month 24			
	Baguera		Control		Baguera		Control	
	n	%	n	%	n	%	n	%
Definitely	147	81%	81	89%	146	82%	75	90%
Probably	22	12%	8	9%	15	8%	5	6%
Possibly	8	4%	2	2%	9	5%	1	1%
Probably Not	3	2%	0	0%	6	3%	1	1%
Definitely Not	1	1%	0	0%	1	1%	1	1%
Source: Tables Clinical Follow-up.sas; Analyzed: 19JUN2026								

Radiographic Assessments – Quantitative
Angular Motion

Angular motion (rotation) at the index level was assessed using the definition of the change in angle between the adjacent endplates of the motion segment in the sagittal plane from flexion to extension. Table 43 presents the angular motion at the index level in the mITT Analysis Set. In the investigational group, mean angular motion increased from 8.5 degrees at screening to 11.3 degrees at Month 24. In the control group, mean angular motion increased from 8.0 degrees at screening to 10.5 degrees at Month 24.

Table 43 Angular Motion (Index Level) [degrees] (mITT Analysis Set, N=285)

	BAGUERA® C						Control						Group Difference	
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	Dif	p*
Screening	173	8.5	4.7	7.8	0.3	20.4	87	8.0	4.5	7.6	0.7	19.8	0.5	0.207
Week 06	175	9.5	4.5	9.5	0.3	21.3	85	9.2	3.9	8.7	0.1	21.4	0.2	0.344
Month 03	173	10.8	4.5	10.6	0.5	22.4	87	11.0	4.9	11.2	0.0	21.7	-0.2	0.326
Month 06	176	11.5	4.6	11.5	0.2	22.3	89	11.6	4.7	10.7	2.2	21.3	0.0	0.486
Month 12	170	11.3	5.2	11.4	0.4	21.6	89	11.1	5.4	10.8	0.6	23.0	0.2	0.396
Month 24	168	11.3	5.6	10.8	0.1	23.2	80	10.5	5.7	9.8	0.2	22.4	0.9	0.123

*Two-sided 95% Wilcoxon Rank Sum test.
Source: Tables Radiography - sas; Analyzed: 29JUN2026

Translational Motion

Translational motion at the index level was assessed using the definition of displacement of the posterior-inferior corner of the superior vertebra in a direction defined parallel to the superior endplate of the inferior vertebra from flexion to extension.

Table 44 presents the amount of translational motion at the index level in the mITT Analysis Set. In the investigational group, mean translational motion increased from 0.9 mm at screening to 1.3 mm at Month 24. In the control group, mean translational motion increased from 0.9 mm at screening to 1.4 mm at Month 24.

Table 44 Translational Motion (Index Level) [mm] (mITT Analysis Set, N=285)

	BAGUERA® C						Control						Group Difference	
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	Diff.	p*
Screening	173	0.9	0.6	0.8	0.0	3.1	87	0.9	0.6	0.7	0.0	2.6	0.0	0.228
Week 06	175	1.1	0.5	1.1	0.0	2.9	85	1.2	0.6	1.2	0.0	3.3	-0.2	0.039
Month 03	173	1.3	0.6	1.2	0.0	2.6	87	1.5	0.8	1.5	0.0	3.4	-0.2	0.009
Month 06	176	1.4	0.6	1.3	0.0	3.4	89	1.6	0.8	1.5	0.3	3.7	-0.2	0.034
Month 12	170	1.3	0.7	1.3	0.0	3.3	89	1.5	0.9	1.4	0.1	3.6	-0.2	0.096
Month 24	168	1.3	0.8	1.3	0.0	5.5	80	1.4	0.9	1.2	0.0	3.7	0.0	0.447

*Two-sided 95% Wilcoxon Rank Sum test.
Source: Tables Radiography.sas; Analyzed: 29JUN2026

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 is calculated as the simple mean of the anterior and posterior disc heights.

Table 45 describes the average disc height at the index level in the mITT Analysis Set. In the investigational group, the mean average disc height increased from 3.1 mm at screening to 5.5mm at Month 24. In the control group, the mean average disc height increased from 3.3 mm at screening to 5.2 mm at Month 24.

Table 45 Average Disc Height (Index Level) [mm] (mITT Analysis Set, N=285)

	BAGUERA® C						Control						Group Difference	
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	Dif	p*
Screening	182	3.1	0.7	3.1	0.7	4.7	94	3.3	0.8	3.3	1.8	7.1	-0.2	0.086
Post-Operative / Discharge	141	6.0	0.6	6.0	4.6	7.8	69	5.8	0.8	5.8	3.5	8.2	0.2	0.026
Week 06	183	5.6	0.6	5.6	4.2	7.7	94	5.3	0.8	5.2	3.1	7.8	0.4	<.001
Month 03	177	5.6	0.5	5.6	4.1	7.3	91	5.3	0.8	5.2	3.1	7.8	0.4	<.001
Month 06	183	5.6	0.6	5.6	4.1	7.6	92	5.2	0.8	5.2	3.1	7.7	0.4	<.001
Month 12	175	5.6	0.6	5.5	4.0	7.6	91	5.2	0.8	5.2	3.0	7.5	0.4	<.001
Month 24	173	5.5	0.6	5.5	4.0	7.3	82	5.2	0.8	5.1	3.0	7.4	0.4	<.001
*Two-sided 95% Wilcoxon Rank Sum test. Source: Tables Radiography.sas; Analyzed: 29JUN2026														

Disc Angle

Disc angle is defined as the angle formed between the endplates of adjacent vertebrae with the subject in a neutral neck position. A disc angle greater than 0 degrees corresponds to local lordosis and a disc angle less than 0 degrees corresponds to local kyphosis. Table 46 presents the disc angle at the index level in the mITT Analysis Set. In the investigational group, mean disc angle increased from 1.4 degrees at screening to 7.5 degrees at Month 24. In the control group, mean disc angle increased from 1.7 degrees at screening to 7.1 degrees at Month 24.

Table 46 Disc Angle (Index Level) [degrees] (mITT Analysis Set, N=285)

	BAGUERA® C						Control						Group Difference	
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	Dif	p*
Screening	182	1.4	4.1	0.8	-7.9	14.0	94	1.7	3.4	1.7	-6.0	11.9	-0.3	0.214
Post-Operative / Discharge	141	10.3	3.7	10.7	2.1	19.0	69	10.0	4.1	10.3	-5.0	20.2	0.3	0.341
Week 06	183	7.2	4.9	6.8	-6.8	18.8	94	6.7	4.4	5.9	-3.7	15.8	0.5	0.235
Month 03	177	7.3	4.7	7.3	-3.8	19.5	91	7.0	4.7	6.5	-2.8	18.0	0.3	0.308
Month 06	183	7.5	4.5	7.4	-3.2	18.3	92	6.8	5.1	7.5	-8.1	17.0	0.7	0.225
Month 12	175	7.0	4.8	6.8	-3.8	18.0	91	7.1	4.7	7.0	-5.0	17.2	-0.1	0.428
Month 24	173	7.5	4.6	7.5	-5.2	19.0	82	7.1	5.0	6.9	-4.0	19.2	0.4	0.308

*Two-sided 95% Wilcoxon Rank Sum test.
Source: Tables Radiography.sas; Analyzed: 29JUN2026

Radiographic Assessments – Qualitative

Device Condition

Based upon the radiographic data, device condition was assessed at each timepoint from Month 3 to Month 24. All devices were assessed to be intact (i.e., no evidence of device disassembly, fracture, or loosening).

Table 47 identifies the device condition classification at the index level in both groups. The totality of devices were assessed to be intact at each follow-up timepoint to Month 24. There was no evidence of device disassembly or fracture in either group.

Table 47 Device Condition (mITT Analysis Set, N=285)

	Month 03				Month 06				Month 12				Month 24			
	BAGUERA® C		Control		BAGUERA® C		Control		BAGUERA® C		Control		BAGUERA® C		Control	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Intact	183	100%	93	100%	186	100%	92	100%	178	100%	92	100%	175	100%	83	100%
Disassembled	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Fractured	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Loose	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Indeterminate	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Unable to assess	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Not Applicable	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Not Required	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Source: Tables Radiography.sas; Analyzed: 29JUN2026																

Device Migration

Based upon the radiographic data, device migration was assessed at each timepoint from Month 3 to Month 24 (see Table 48 below). All BAGUERA® C devices were assessed to have no evidence of migration, while in the control group one (1) device was assessed to have migrated (i.e. presence of AP or lateral change in implant position greater than or equal to 3mm) at Month 6.

Table 48 Device Migration (mITT Analysis Set, N=285)

	Month 03				Month 06				Month 12				Month 24			
	BAGUERA® C		Control		BAGUERA® C		Control		BAGUERA® C		Control		BAGUERA® C		Control	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Absent	183	100%	93	100%	186	100%	91	99%	178	100%	92	100%	175	100%	83	100%
Present - Migration	0	0%	0	0%	0	0%	1	1%	0	0%	0	0%	0	0%	0	0%
Present - Extrusion	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Indeterminate	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Unable to assess	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Not Applicable	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Not Required	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Source: Tables Radiography.sas; Analyzed: 29JUN2026																

Device Subsidence

Based upon the radiographic data, device subsidence was assessed at each timepoint from Month 3 to Month 24 (see Table 49 below). All devices in both groups were assessed to have no subsidence (i.e., no evidence of cranial or caudal subsidence of the implant greater than 2mm) at all follow-up timepoints.

Table 49 Device Subsidence (mITT Analysis Set, N=285)

	Month 03				Month 06				Month 12				Month 24			
	BAGUERA® C		Control		BAGUERA® C		Control		BAGUERA® C		Control		BAGUERA® C		Control	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Absent	183	100%	93	100%	186	100%	92	100%	178	100%	92	100%	175	100%	83	100%
Cranial/Caudal Subsidence > 2 mm	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Indeterminate	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Unable to assess	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Not Applicable	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Not Required	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Source: Tables Radiography.sas; Analyzed: 29JUN2026																

Heterotopic Ossification

Based upon the radiographic data, heterotopic ossification (HO) was assessed at each timepoint from Month 3 to Month 24 (see Table 50 below). 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 50 identifies the findings related to HO at each timepoint at the index level. There is increasing progression of HO over time, with Class II HO being the predominant type at later timepoints. A total of 39% (68/174) of investigational devices and 63% (52/83) of control devices were assessed to have Class II HO at Month 24.

Table 50 Heterotopic Ossifcation (mITT Analysis Set, N=285)

	Month 03				Month 06				Month 12				Month 24			
	BAGUERA® C		Control		BAGUERA® C		Control		BAGUERA® C		Control		BAGUERA® C		Control	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
None	172	95%	88	95%	153	83%	71	77%	109	62%	48	52%	65	37%	19	23%
Class I	7	4%	4	4%	9	5%	7	8%	15	8%	2	2%	22	13%	3	4%
Class II	3	2%	1	1%	21	11%	14	15%	47	27%	39	42%	68	39%	52	63%
Class III	0	0%	0	0%	2	1%	0	0%	5	3%	2	2%	16	9%	6	7%
Class IV	0	0%	0	0%	0	0%	0	0%	1	1%	1	1%	3	2%	3	4%
Indeterminate	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Unable to assess	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Not Applicable	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Not Required	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Source: Tables Radiography.sas; Analyzed: 29JUN2026																

Adjacent level Disc Degeneration (Kellgren-Lawrence)

Based upon the radiographic data, adjacent level disc degeneration (ALDD) was evaluated at each timepoint from Month 3 to Month 24. 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 51 reports the findings related to ALDD at Month 12 and Month 24 at the level above the index level. There is an increase in ALDD over time in both groups. However, only 1.1% (2/175) of investigational subjects and no (0%) control subjects are classified to have severe ALDD at Month 24.

Table 51 Adjacent Level DD in the level above the index level (mITT Analysis Set, N=285)

	Month 12				Month 24			
	BAGUERA® C		Control		BAGUERA® C		Control	
	n	%	n	%	n	%	n	%
None	98	55%	48	52%	80	46%	36	43%
Doubtful	38	21%	24	26%	37	21%	23	28%
Minimal	27	15%	14	15%	45	26%	18	22%
Moderate	13	7%	6	7%	10	6%	6	7%
Severe	1	1%	0	0%	2	1%	0	0%
Indeterminate	0	0%	0	0%	0	0%	0	0%
Unable to assess	1	1%	0	0%	1	1%	0	0%
Not Applicable	0	0%	0	0%	0	0%	0	0%
Not Required	0	0%	0	0%	0	0%	0	0%
Source: Tables Radiography.sas; Analyzed: 29JUN2026								

Table **52** reports the findings related to ALDD at Month 12 and Month 24 at the level below the index level. There is an increase in ALDD over time in both groups. However, only 1.1% (2/175) of investigational subjects and 1.2% (1/83) control subjects are classified to have severe ALDD at Month 24.

Table 52 Adjacent Level DD in the level below the index level (mITT Analysis Set, N=285)

	Month 12				Month 24			
	BAGUERA® C		Control		BAGUERA® C		Control	
	n	%	n	%	n	%	n	%
None	102	57%	50	54%	81	46%	34	41%
Doubtful	25	14%	20	22%	26	15%	18	22%
Minimal	21	12%	5	5%	27	15%	8	10%

Moderate	10	6%	3	3%	12	7%	2	2%
Severe	1	1%	0	0%	2	1%	1	1%
Indeterminate	18	10%	13	14%	26	15%	19	23%
Unable to assess	1	1%	1	1%	1	1%	1	1%
Not Applicable	0	0%	0	0%	0	0%	0	0%
Not Required	0	0%	0	0%	0	0%	0	0%
Source: Tables Radiography.sas; Analyzed: 29JUN2026								

Subgroup Analyses

The study was not specifically powered for any subgroup analyses.

Pediatric Extrapolation

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

c) 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 91 investigators of which none were full-time or part-time employees of the sponsor and ten of the clinical investigators had disclosable financial interests/arrangements as defined in sections 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: One
- Significant payment of other sorts: Nine
- Proprietary interest in the product tested held by the investigator: None
- Significant equity interest held by investigator in sponsor of covered study: None

The applicant 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.

B. Two-Contiguous Level Cervical Disc Replacement

1. Pivotal Study Design

Subjects in the pivotal clinical trial were treated between February 2021 and April 2024. The prospective, multi-center, randomized, controlled study was conducted under IDE G200239 to compare the BAGUERA® C Cervical Disc Prosthesis (investigational device) to the Mobi-C® Cervical Disc (control device), a PMA approved artificial cervical disc.

The database for this PMA reflects data collected on a total of 335 subjects that signed the informed consent and were randomized in the study; of the 335 subjects, 26 of these subjects, remained blinded, and ultimately were not treated. The remaining 309 of these subjects (N=211 BAGUERA® C; and N=98 Mobi-C) had an incision time recorded and were enrolled in the study. Subjects were treated at 25 US sites. Subjects were randomized in a 2:1 ratio to the two-level BAGUERA® C device (investigational group) or to the two-level Mobi-C device (control group), respectively. A statistical plan was designed to test non-inferiority between the two groups.

a) 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 as identified in Table 4 with the following exceptions:

- Inclusion Criterion #3 required symptomatic cervical disc disease (SCDD) at two contiguous levels from C3 to C7 (versus one level); Exclusion Criterion #5 prohibited prior spine surgery at the operative levels (versus level); and
- Exclusion Criterion #14 excluded subjects with symptomatic SCDD or significant cervical spondylosis at more than two levels (versus one level).

b) Control

Control subjects were prospectively enrolled and randomized to treatment with the Mobi-C® Cervical Disc (N=98), a PMA-approved artificial cervical disc. The Mobi-C® Cervical Disc was implanted according to its surgical technique guide.

c) 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 6 weeks (±2 weeks), 3 months (±2 weeks), 6 months (±1 month), 1 year (±2 months), 2 years (±2 months), and annually thereafter (±2 months). The following parameters (Table 53) were measured throughout the study:

Table 53 BAGUERA® C Cervical Disc Prosthesis IDE G200239 Study Assessment Schedule

Procedures	**Pre-op**	**Surgery**	**6 Weeks** ± 2 wks	**3 Months** ± 2 wks	**6 Months** ± 4 wks	**12 Months** ± 8 wks	**24 Months** ± 8 wks	**Annual to 84 Months** ± 8 wks	**Unscheduled**
Informed consent	X	-	-	-	-	-	-	-	-
Demographics	X	-	-	-	-	-	-	-	-
Medical History	X	-	X	X	X	X	X	X	X
Work Status	X	-	X	X	X	X	X	X	-
Incl/Excl criteria	X	-	-	-	-	-	-	-	-
Randomization	X	-	-	-	-	-	-	-	-
Pregnancy Assessment	-	X	-	-	-	-	-	-	-
MRI or CAT scan	X	-	-	-	-	-	-	-	-
DEXA scan	X	-	-	-	-	-	-	-	-
AP Lat X-rays	X	X	X	X	X	X	X	X	-
Flex-Ext X-rays	X	-	X	X	X	X	X	X	-
Presenting Symptoms	X	-	X	X	X	X	X	X	-
Neuro Exam	X	X	X	X	X	X	X	X	X
Nurick Classification	X	-	-	-	-	-	-	-	-
Odom's Classification	-	-	-	-	-	-	X	X	-
NDI	X	-	X	X	X	X	X	X	X
Neck VAS	X	-	X	X	X	X	X	X	X
Left/Right Arm VAS	X	-	X	X	X	X	X	X	X
SF-12v2	X	-	-	-	X	X	X	X	-
Patient Satisfaction	-	-	X	X	X	X	X	X	-
Dysphagia Index	X	-	X	X	X	X	X	X	-
Medications	X	X	X	X	X	X	X	X	X
Adverse Events	-	X	X	X	X	X	X	X	X

d) Clinical Endpoints

The safety of the BAGUERA® C Cervical Disc Prosthesis 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, seriousness and relationship to the implant and/or surgical procedure), subsequent index level surgical procedures and maintenance or improvement in neurological status.

The effectiveness of the BAGUERA® C Cervical Disc Prosthesis was assessed using a composite endpoint, as described below. Effectiveness was evaluated by assessing improvement in the Neck Disability Index (NDI), neck and arm pain Visual Analogue Scale (VAS) questionnaires, health-related quality of life using the short-form questionnaire (SF-12v2), Dysphagia Handicap Index (DHI), Odom's Criteria, and patient satisfaction of the BAGUERA® C Cervical Disc Prosthesis group compared to the Mobi-C control group. Similar criteria were used to measure success in both groups.

Primary Endpoint

The study hypothesis for the BAGUERA® C Cervical Disc Prosthesis IDE G200239 Study was that the Month 24 (i.e., 24 months post-operatively) composite clinical success (CCS) rate of the two-contiguous-level BAGUERA® C Cervical Disc Prosthesis would be no worse than conventional two-contiguous-level MOBI-C® Cervical Disc when success is evaluated at Month 24 in patients with intractable radiculopathy (arm pain and/or a neurological deficit) with neck pain or myelopathy due to abnormalities localized at two-contiguous-level from C3 to C7 that is unresponsive to conservative management or have presence of progressive signs or symptoms of nerve root/spinal cord compression.

Individual CCS for both the investigational and control groups was defined as:

1. Improvement in pain and function, as measured through the Neck Disability Index (NDI), of at least 15 percentage points (out of 100%) from pre-operative;
2. Maintenance or improvement in neurological status at 24 months compared to baseline (as determined by the CEC)
3. No secondary surgical intervention defined as revision, removal, reoperation, or supplemental fixation at the index level
4. No serious adverse event(s) confirmed as device or procedure related (as determined by the CEC).

Subjects who required device removal (explantation) were withdrawn from the study and were considered a treatment failure. In addition, subjects who

required a secondary surgical intervention (SSI) at any of the index levels were considered a treatment failure.

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: $\pi_T - \pi_C \leq -0.125$ (the CCS rate of investigational device was clinically inferior to control)

H_a: $\pi_T - \pi_C > -0.125$ (the CCS rate of investigational device was not clinically inferior to control)

where π_T and π_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, $\delta = 0.125$.

The claim of non-inferiority was pre-specified to be accepted if the posterior probability of non-inferiority, is greater than or equal to 0.95. That is, if, $Pr(\pi T - \pi C > -0.125 \mid \text{Trial Results}) \geq 0.95$.

This posterior probability is calculated using Beta(1, 1) non-informative priors for both the investigational and control arms. A Bayesian posterior probability threshold of 0.95 controls type 1 error to 0.05 with statistical power in excess of 80%.The definitions for secondary surgical intervention classifications (reoperation, revision, removal, and supplemental fixation) are provided in the single-level study section (see Section A.1.d).

Secondary Endpoints

Secondary endpoints, measured in both treatment groups, included:

- Time to recovery (time to first 15 percentage points – out of 100 NDI – improvement)
- Left and right arm pain 100mm Visual Analogue Scale (VAS) (an improvement in pain of at least 20mm on the VAS is considered clinically significant)
- Neck pain 100mm Visual Analogue Scale (VAS) (an improvement in pain of at least 20mm on the VAS is considered clinically significant)
- Health Related Quality of Life (SF-12v2) Physical Component Summary (PCS)
- Patient Satisfaction
- Dysphagia handicap Index (24 months compared to baseline)
- Odom's Criteria to measure surgical success (determined by the treating physician)

Other Clinical Measures:

Other clinical measures, evaluated in both treatment groups, included:

- Operative time
- Estimated blood loss
- Length of hospital stay
- Work status

Radiographic Assessments:

Radiographic assessments (performed by an independent imaging core lab), evaluated in both treatment groups, included:

- Quantitative Assessment included:
  - Angular Motion
  - Translational Motion
  - Anterior/Posterior/Average Disc Height and Change in Disc Height
  - Disc Angle and Change in Disc Angle
- Qualitative Assessment included:
  - Heterotopic Ossification (including bridging bone)
  - Device Condition
  - Device Migration
  - Device Subsidence
  - Superior Interface Radiolucency
  - Inferior Interface Radiolucency
  - Bone-Implant Interface Motion
  - Adjacent Level Disc Degeneration
  - Additional Radiographic Observations

e) Clinical Events Committee

A CEC was utilized for the BAGUERA® C Cervical Artificial Disc IDE study to mitigate reporting bias of safety-related events. The CEC was comprised of three (3) independent spine surgeons, and a CEC charter was used to define the role of the CEC. The committee was responsible for adjudication of AE (i.e., relationship to device/procedure, seriousness, determination of unanticipated adverse device effects), secondary surgical intervention (SSI) (i.e., classification of revision, removal, reoperation or supplemental fixation), protocol deviations (i.e., classification as Major or Minor), and neurological success criterion (classification of neurologic status at Month 24 as compared to baseline).

2. Accountability of PMA Cohort

At the time of the May 13, 2026 database lock, a total of 335 subjects signed the informed consent form and were randomized (Intent-to-Treat Analysis Set):

- A total of 26 subjects were randomized, remained blinded, and ultimately not treated.
    - A total of 16 of the 26 subjects withdrew their consent prior to undergoing study treatment.
    - A total of 5 of the 26 subjects no longer met the study eligibility criteria
    - A total of 5 of the 26 subjects were withdrawn by the investigator prior to undergoing study treatment.

The resulting 309 available randomized subjects, with an operation date at the time of the database lock (n=211 BAGUERA® C subjects and n=98 Mobi-C control subjects) were assessed as part of the modified Intent-to-Treat (mITT) Analysis Set. The mITT population includes one subject randomized to the BAGUERA® C group who was converted intra-operatively to fusion. Within the mITT analysis set, two subjects were implanted on the same date and received the opposite device compared to the randomization assignment. Therefore, the As-Treated (AT) Analysis Set includes 308 subjects (n=210 BAGUERA® C subjects and n=98 Mobi-C control subjects). The Per-Protocol (PP) analysis set includes 307 subjects (n=209 BAGUERA® C subjects and n=98 Mobi-C control subjects). One subject in the BAGUERA® C group was excluded from the PP analysis set as after being treated it was determined that eligibility in the study was not met. This information is presented in tabular form in Table 54 below; similarly, this information is presented graphically via a patient accounting tree in Figure 5 below.

Table 54 Accounting Information – G200239 study (two-level)

	BAGUERA® C	**Mobi-C**
Randomized (ITT Population)	227	108
Subjects randomized but not treated	16	10
Modified Intention-to-Treat (mITT) Population	211	98
As Treated (AT) Population	210	98
Per Protocol (PP) Population	209	98
Subjects with known primary outcome (CCS) among mITT population	192	85
Subjects with missing CCS outcome among mITT population: - Not yet overdue (between day 730 and 790): - Missing for other reason: o Lost to Follow-up: o Death: o Missed 24 Month Visit: o Subject withdrew consent:	17 0 8 1 6 2	13 1 9 0 3 0

This submission includes data up to the database lock that occurred on May 13, 2026. The Month 24 CCS endpoint within the PP Analysis Set is based on 99.7%

(306/307) of all subjects expected due. Within the PP Analysis Set, 100% (209/209) of BAGUERA® C subjects, and 100% (98/98) of Mobi-C subjects are theoretically due (Day 730); within this same analysis set, 92% (192/209) of BAGUERA® C subjects, and 87% (85/98) of Mobi-C subjects have a known primary outcome.

The subject accountability summary through the Month 24 timepoint is presented in Table 55 for the PP Analysis Set. The accounting table is stratified by treatment arm with the overall BAGUERA® C group subjects referred to hereafter as the investigational group ("I"), and Control group ("C") for subjects that have completed follow up through Month 24.

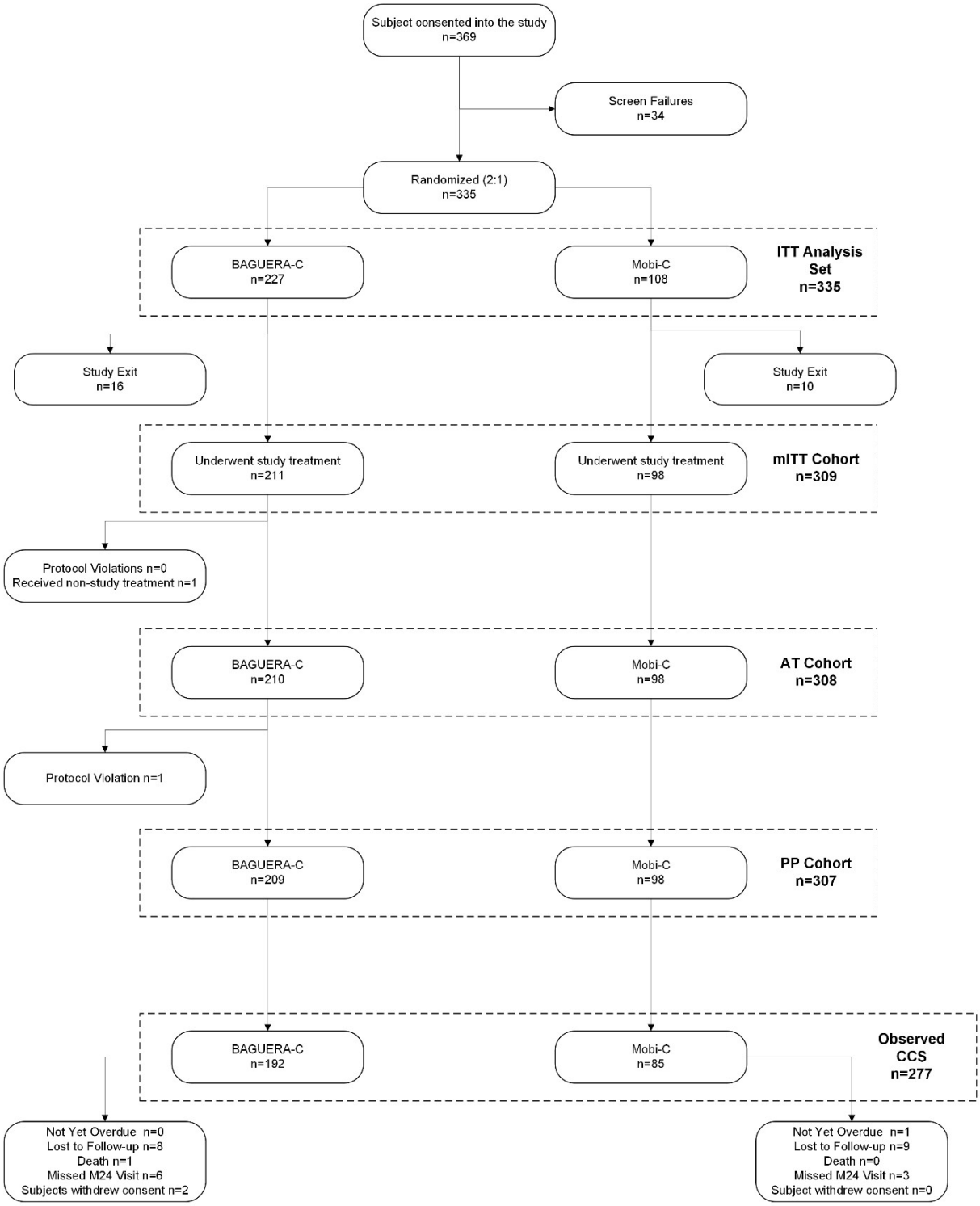

Figure 5 IDE Study G200239 (two-level). Subject Accountability Tree.

Table 55 G200239 – Subject Accounting Summary Through Month 24 for the PP Analysis Set

	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
Accounting														
(1) Theoretical follow-up	209	98	209	98	209	98	209	98	209	98	209	98	209	98
(2) Cumulative Death			0	0	0	0	0	0	0	0	0	0	1	0
(3) Cumulative SSI Failures			0	0	1	2	2	2	3	2	4	4	4	4
(4) Not Yet Overdue			0	0	0	0	0	0	0	0	0	0	0	1
(5) Deaths+SSI failures among theoretically due			0	0	1	2	2	2	3	2	4	4	5	4
(6) Expected Due [(6)=(1)-(4)-(5)]					208	96	207	96	206	96	205	94	204	93
(7) SSI failures among theoretically due			0	0	1	2	2	2	3	2	4	4	4	4
(8) Expected due+SSI failures among theoretically Due [(8)=(6)+(7)]					209	98	209	98	209	98	209	98	208	97
All Evaluated Accounting (Actual[B]) Among Expected Due Procedures														
(9) Procedures with any clinical data in interval†	209	98			207	95	202	93	200	92	198	88	188	82
(10) Visit Compliance (%)					100%	99%	98%	97%	97%	96%	97%	94%	92%	88%
(11) Change in NDI							202	93	199	91	198	88	188	81
(12) Composite Clinical Success (CCS)													188	81
(13) Actual[B] % Follow-up for CCS													92%	87%
Within Window Accounting (Actual[A]) Among Expected Due Procedures														
(14) Procedures with any clinical data in interval†	209	98			142	66	180	83	147	57	183	87	168	74
(15) Visit Compliance (%)					68%	69%	87%	86%	71%	59%	89%	93%	82%	80%
(16) Change in NDI							180	83	147	56	183	87	168	73
(17) Composite Clinical Success (CCS)													168	73
(18) Actual[A] % Follow-up for CCS													82%	78%
Composite Clinical Success														
(19) Composite Clinical Success (CCS)													192	85
(20) Actual[A] % Follow-up for CCS													92%	87%

†NDI value at baseline, change in NDI at follow-up visits.
Source: Tables Follow-up Compliance 2L - PP.sas; Analyzed: 15JUN2026

The following definitions apply to **Table 55** above:

[1] **Theoretical follow-up**: The theoretical follow-up is the number of subjects treated that would have been examined if all subjects returned on the exact anniversary of their respective initial treatment dates. The theoretical follow-up is determined by selecting a date of database closure (i.e., the date the database was closed to the addition of information). The theoretical row is the treated subjects less those not yet due for a follow-up visit. The date of database closure for the analysis will be listed at the top of the table.

[2] **Cumulative Deaths**: Cumulative deaths up to the date of the exact anniversary defining the current interval. Deaths occurring after the exact anniversary are recorded in the next interval. Although the cumulative numbers of deaths are recorded on this row, only deaths among subjects that are theoretically due for that interval are subtracted from theoretically due to determine the number expected due for clinical index evaluation.

[3] **Cumulative Secondary Surgical Intervention (SSI) Failures**: Cumulative SSI failures up to the date of the exact anniversary defining the current interval. SSI failures occurring after the exact anniversary are recorded in the next interval. Although the cumulative numbers of SSI failures are recorded on this row, only additional events among subjects that are theoretically due for that interval are subtracted from theoretically due to determine the number expected due for clinical index evaluation.

[4] **Not Yet Overdue**: Includes subjects whose treatment anniversary has occurred; however, clinical data has not yet been collected (e.g., NDI is currently unavailable), but the patient is still in the protocol-specified follow-up window. Such subjects may yet be observed, and so follow-up compliance estimates account for this by removing such subjects from the denominator as well as from the numerator when determining compliance ratios.

[5] **Deaths + Cumulative Secondary Surgical Intervention Failures among theoretically due**: This row records the sum of deaths and Secondary Surgical Interventions among those theoretically due for follow-up according to the exact anniversary of the scheduled follow-up visit.

[6] **Expected due for clinic visit**: This row is the number of subjects expected for a given time interval. These include the theoretical number of subjects who are due to be evaluated, less the number of subjects who died, and less the number of subjects in the "Not yet overdue" category. Expected = Theoretical - [Deaths + SSI Failures + Not yet overdue] where the counts of the numbers of deaths and Not Yet Overdue are determined from among the theoretically due subjects. This row serves as the denominator for evaluation % follow-up for clinical indices (e.g., NDI). The Expected row includes subjects lost to follow-up, and major protocol violations are included in the expected group for all time points.

[7] **SSI Failures among theoretically due:** This row records the Secondary Surgical Interventions among those theoretically due for follow-up according to the exact anniversary of the scheduled follow-up visit.

[8] **Expected due + SSI Failures among theoretical due:** Expected due plus theoretical due Failures is computed by adding expected due in row (6) to the number of cumulative Failures among theoretically due devices in row (7). This row serves as the denominator for composite clinical success (CCS) outcomes since CCS status is known for subjects with a Failure as defined in row (3).

[9] **Procedures with any clinical data in the interval**: The number of subjects with any clinical data for all evaluated subjects among expected due procedures. If any case report is recorded with a date, the subject will be considered to have contributed any data in the interval.

[10] **Visit Compliance among expected (%)**: The percentage of subjects compliant with the specified visit scheduled for all evaluated subjects among expected due procedures. This rate will not necessarily equal the primary observed endpoint data.

[11] **Change in NDI**: The number of subjects reporting a change in NDI for all evaluated subjects among expected due procedures. Subjects without baseline NDI can never contribute to this row.

[12] **Composite Clinical Success (CCS):** These rows indicate the number of subjects with enough data available for evaluation of clinical composite success for all evaluated subjects among expected due procedures (12)

[13] **Actual [B] follow-up for CCS(%)**: The number of subjects with Month 24 CCS data among all subjects enrolled in the study. This will be the primary measure of study compliance.

[14] **Procedures with any clinical data in the interval**: Repeats (9) restricted to evaluations performed within the interval.

[15] **Visit Compliance among expected (%)**: Repeats (10) restricted to evaluations performed within the interval.

[16] **Change in NDI**: Repeats (11) restricted to evaluations performed within the interval.

[17] **Composite Clinical Success (CCS):** These rows indicate the number of subjects with enough data available for evaluation of clinical composite success for all subjects that are within window among expected due procedures (21).

[18] **Actual [A] follow-up for CCS (%)**: Repeats (13) restricted to evaluations performed within the interval.

[19] **Composite Clinical Success:** The number of subjects with primary endpoint data (Month 24 CCS), including terminal failures from SSIs, amongst all subjects enrolled in the study. This is the primary analysis set.

[20] **Actual [A] Follow-up for CCS:** The proportion of subjects with primary endpoint data, including terminal failures from SSIs, amongst all subjects enrolled in the study.

3. 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 contiguous-level indications in the US.

Table 56 Baseline Demographic Continuous Variables (mITT Analysis Set, N=309)

	BAGUERA® C						Mobi-C						Group Difference*			
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	Δ	LB	UB	p
All																
Age (years)	211	47.9	9.2	47.0	25.0	69.0	98	48.9	9.6	49.0	27.0	69.0	-1.0	-3.2	1.3	0.182
BMI (kg/m^2)	211	29.1	5.1	28.6	17.1	40.0	98	28.8	4.7	28.8	18.1	40.0	0.3	-0.9	1.5	0.389
Height (in)	211	68.2	4.1	68.5	57.0	83.0	98	68.2	3.9	69.0	59.0	78.0	0.0	-0.9	1.0	0.438
Weight (lbs)	211	193.6	41.5	190.0	103.0	335.0	98	191.3	37.7	195.0	106.0	290.0	2.2	-7.1	11.6	0.493
Female																
Age (years)	90	47.4	9.3	47.0	28.0	69.0	37	48.6	10.0	49.0	27.0	68.0	-1.2	-4.9	2.6	0.224
BMI (kg/m^2)	90	28.9	5.8	28.8	17.1	40.0	37	29.0	6.0	27.5	18.1	39.3	-0.1	-2.4	2.2	0.447
Height (in)	90	64.8	2.5	65.0	59.0	70.0	37	64.7	2.8	65.0	59.0	71.5	0.1	-0.9	1.2	0.321
Weight (lbs)	90	172.5	35.0	169.3	103.0	263.0	37	173.1	39.1	170.0	106.0	240.0	-0.6	-15.2	13.9	0.481
Male																
Age (years)	121	48.2	9.2	47.0	25.0	69.0	61	49.0	9.4	49.0	28.0	69.0	-0.8	-3.7	2.1	0.314
BMI (kg/m^2)	121	29.3	4.6	28.5	20.3	39.9	61	28.7	3.8	28.9	21.0	40.0	0.6	-0.7	1.9	0.298
Height (in)	121	70.8	3.1	70.0	57.0	83.0	61	70.3	2.7	70.0	65.0	78.0	0.4	-0.4	1.3	0.227
Weight (lbs)	121	209.2	39.0	204.2	140.0	335.0	61	202.4	32.5	200.0	138.0	290.0	6.9	-3.9	17.6	0.212
Clinical Scores																
NDI	210	58.0	15.2	58.0	30.0	94.0	98	60.5	15.9	60.0	30.0	100.0	-2.5	-6.3	1.3	0.124
VAS Neck Pain	210	75.0	18.0	77.5	1.0	100.0	98	77.4	18.3	81.0	13.0	100.0	-2.4	-6.7	2.0	0.093
VAS Right Arm Pain	210	44.2	37.0	46.5	0.0	100.0	98	52.8	35.4	59.5	0.0	100.0	-8.5	-17.1	0.1	0.023
VAS Left Arm Pain	210	56.2	33.8	68.5	0.0	100.0	98	53.5	36.2	66.0	0.0	100.0	2.7	-5.8	11.2	0.271
DHI Score	210	8.0	12.3	4.0	0.0	70.0	98	10.1	15.3	4.0	0.0	92.0	-2.1	-5.5	1.4	0.134
SF-12v2 PCS	209	32.2	6.4	32.0	16.1	47.6	98	32.6	5.8	32.9	16.7	42.8	-0.4	-1.9	1.0	0.223
SF-12v2 MCS	209	46.0	12.9	46.6	16.3	74.6	98	44.2	13.0	44.6	18.1	72.9	1.9	-1.2	5.0	0.133

*Device group mean differences and 95% Confidence Intervals with Wilcoxon p-value
Source: Tables Baseline Demo.sas; Analyzed: 08JUL2026

Table 57 Summary of Baseline and Demographic Categorical Variables – mITT Analysis Set

	BAGUERA® C			Mobi-C			Group Difference		
	N	n	%	N	n	%	Dif	95% LB	95% UB
Sex									
Female	211	90	42.7%	98	37	37.8%	4.9%	-6.8%	16.6%
Male	211	121	57.3%	98	61	62.2%	-4.9%	-16.6%	6.8%
Race									
American Indian or Alaska Native	211	1	0.5%	98	1	1.0%	-0.5%	-2.7%	1.6%
Asian	211	6	2.8%	98	3	3.1%	-0.2%	-4.3%	3.9%
Black or African American	211	6	2.8%	98	5	5.1%	-2.3%	-7.2%	2.6%
Native Hawaiian or Other Pacific Islander	211	1	0.5%	98	0	0.0%	0.5%	-0.5%	1.4%
Unknown/Not Reported	211	1	0.5%	98	0	0.0%	0.5%	-0.5%	1.4%
White	211	189	89.6%	98	88	89.8%	-0.2%	-7.5%	7.1%
Other	211	7	3.3%	98	1	1.0%	2.3%	-0.8%	5.4%
Ethnicity									
Hispanic or Latino	211	11	5.2%	98	5	5.1%	0.1%	-5.2%	5.4%
Not Hispanic or Latino	211	198	93.8%	98	93	94.9%	-1.1%	-6.5%	4.4%
Unknown/Not Reported	211	2	0.9%	98	0	0.0%	0.9%	-0.4%	2.3%
Nurick Classification[1]									
0	211	168	79.6%	98	79	80.6%	-1.0%	-10.5%	8.5%
1	211	34	16.1%	98	13	13.3%	2.8%	-5.5%	11.2%
2	211	4	1.9%	98	4	4.1%	-2.2%	-6.5%	2.1%
3	211	5	2.4%	98	2	2.0%	0.3%	-3.1%	3.8%
4	211	0	0.0%	98	0	0.0%	0.0%	0.0%	0.0%
5	211	0	0.0%	98	0	0.0%	0.0%	0.0%	0.0%
Symptomatic Cervical Disc Diagnosis									
No	211	0	0.0%	98	0	0.0%	0.0%	0.0%	0.0%
Yes	211	211	100.0%	98	98	100.0%	0.0%	0.0%	0.0%
Cervical Radiculopathy Diagnosis									
No	211	7	3.3%	98	5	5.1%	-1.8%	-6.8%	3.2%
Yes	211	204	96.7%	98	93	94.9%	1.8%	-3.2%	6.8%
Cervical Myelo-Radiculopathy Diagnosis									
No	211	185	87.7%	98	86	87.8%	-0.1%	-7.9%	7.8%

	BAGUERA® C			Mobi-C			Group Difference		
	N	n	%	N	n	%	Dif	95% LB	95% UB
Yes	211	26	12.3%	98	12	12.2%	0.1%	-7.8%	7.9%
Previous Spine Surgeries									
No	211	179	84.8%	98	82	83.7%	1.2%	-7.6%	9.9%
Yes	211	32	15.2%	98	16	16.3%	-1.2%	-9.9%	7.6%
Relevant General Medical Conditions									
No	211	59	28.0%	98	24	24.5%	3.5%	-7.0%	13.9%
Yes	211	152	72.0%	98	74	75.5%	-3.5%	-13.9%	7.0%
Current Medications for Cervical Spine									
No	211	48	22.7%	98	21	21.4%	1.3%	-8.6%	11.2%
Yes	211	163	77.3%	98	77	78.6%	-1.3%	-11.2%	8.6%

[1] Nurick Classification (Nurick, 1972): (0) Signs or symptoms of root involvement but without evidence of spinal cord disease; (1) Signs of spinal cord disease but no difficulty in walking; (2) Slight difficulty in walking which did not prevent full-time employment; (3) Difficulty in walking which prevented full-time employment or the ability to do all housework, but which was not so severe as to require someone else's help to walk; (4) Able to walk only with someone else's help or with the aid of a frame; (5) Chair bound or bedridden;
Source: Tables Baseline Demo.sas; Analyzed: 08JUL2026

Table 58 Baseline Work Status (Categorical) – mITT Analysis Set

	BAGUERA® C			Mobi-C			Group Difference		
	N	n	%	N	n	%	Dif	95% LB	95% UB
Preoperative Disability Status									
No	211	198	93.8%	98	94	95.9%	-2.1%	-7.2%	3.0%
Yes	211	13	6.2%	98	4	4.1%	2.1%	-3.0%	7.2%
Preoperative Work Status									
Not working due to neck problem	211	14	6.6%	98	6	6.1%	0.5%	-5.3%	6.3%
Not working voluntarily (retired, student, unemployed, etc.)	211	20	9.5%	98	14	14.3%	-4.8%	-12.8%	3.2%
Not working other than neck problems (describe)	211	5	2.4%	98	2	2.0%	0.3%	-3.1%	3.8%
Working part time due to neck problem	211	8	3.8%	98	2	2.0%	1.8%	-2.1%	5.6%
Working part time voluntarily	211	5	2.4%	98	2	2.0%	0.3%	-3.1%	3.8%
Working full time	211	156	73.9%	98	71	72.4%	1.5%	-9.2%	12.1%
Other	211	3	1.4%	98	1	1.0%	0.4%	-2.2%	3.0%

Source: Tables Baseline Demo.sas; Analyzed: 08JUL2026

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 mITT Analysis Set. Variables summarized include operative time, blood loss and length of stay.

Table 59 Operative Continuous Variables. mITT Analysis Set

	BAGUERA® C						Mobi-C						Group Difference*			
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	Δ	LB	UB	p
All																
Duration of Surgery (min)	211	91.2	28.5	91.0	39.0	197.0	98	92.3	29.6	88.5	45.0	189.0	-1.1	-8.1	5.9	0.398
Estimated Blood Loss (cc)	211	31.5	19.8	25.0	2.0	100.0	98	37.7	36.7	25.0	5.0	275.0	-6.2	-13.9	1.5	0.117
Hospital Length of Stay [days]	211	0.1	0.7	0.0	0.0	8.0	98	0.1	0.6	0.0	0.0	6.0	0.0	-0.2	0.1	0.426
Female																
Duration of Surgery (min)	90	90.6	26.9	94.5	39.0	185.0	37	85.2	26.4	79.0	48.0	151.0	5.4	-4.8	15.5	0.138
Estimated Blood Loss (cc)	90	33.1	21.3	25.0	2.0	100.0	37	32.3	20.1	25.0	5.0	100.0	0.8	-7.0	8.7	0.484
Male																
Duration of Surgery (min)	121	91.7	29.7	89.0	48.0	197.0	61	96.6	30.8	97.0	45.0	189.0	-4.9	-14.3	4.5	0.147
Estimated Blood Loss (cc)	121	30.3	18.5	25.0	5.0	100.0	61	41.0	43.7	25.0	5.0	275.0	-10.7	-22.1	0.8	0.058
*Device group mean differences and 95% Confidence Intervals with Wilcoxon p-value Source: Tables Operative 2L.sas; Analyzed: 19JUN2026																

As evidenced in Table 60 below, the majority of procedures occurred in C5/C6 and C6/C7 for both the BAGUERA® C Cervical Disc Prosthesis subjects and the Mobi-C control subjects.

Table 60 Operative Characteristics (categorical) – mITT Analysis Set.

	BAGUERA® C			Mobi-C			Group Difference		
	N	n	%	N	n	%	Diff.	95% LB	95% UB
Index Levels									
C3-C4 / C4-C5	211	5	2.4%	98	2	2.0%	0.3%	-3.1%	3.8%
C4-C5 / C5-C6	211	32	15.2%	98	14	14.3%	0.9%	-7.6%	9.3%
C5-C6 / C6-C7	211	174	82.5%	98	82	83.7%	-1.2%	-10.1%	7.7%
Source: Tables Operative 2L.sas; Analyzed: 08JUL2026									

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.

4. Safety and Effectiveness Results

a) Safety Results

The analysis of safety was based on the investigational cohort of 210 BAGUERA® C subjects and 98 control subjects through Month 24 evaluation. The key safety outcomes for this study are presented below in Tables 61 to 71. Adverse effects are reported in Tables 62 to 69.

Adverse Events 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 procedure and implant-relatedness, seriousness, and if serious, whether or not the event was anticipated.

Table 61 shows a summary of AE categories and rates between the investigational and control groups in the AT Analysis Set. Overall, similar rates of AEs occurred in the investigational group (65.7% - 138/210) and control group (59.2% - 58/98). SAEs that were considered "definitely" device-related were also comparable between the two groups, where 0.5% (1/210) of investigational subjects had "definitely" device-related SAEs, while 1.0% (1/98) control subjects had "definitely" device-related SAEs. Lastly, the rate of SAEs that were considered "definitely" procedure-related was 1.0% (2/210) in investigational subjects and 2.0% (2/98) in control subjects.

Table 61 Adverse Event Summary – AT Analysis Set (N=308)

	BAGUERA® C (N= 210)			Mobi-C (N= 98)		
	Events	Subjs	%[l]	Events	Subjs	%[l]
All	437	138	65.7%	192	58	59.2%
Device Related[†]	26	17	8.1%	8	7	7.1%
Device Related - Possibly	22	16	7.6%	7	6	6.1%
Device Related - Probably	3	2	1.0%	0	0	0.0%
Device Related - Definitely	1	1	0.5%	1	1	1.0%
Procedure Related[†]	76	53	25.2%	47	24	24.5%
Procedure Related - Possibly	29	22	10.5%	19	11	11.2%
Procedure Related - Probably	14	9	4.3%	10	8	8.2%
Procedure Related - Definitely	33	30	14.3%	18	13	13.3%
Device or Procedure Related[†]	80	56	26.7%	49	24	24.5%

	BAGUERA® C (N= 210)			Mobi-C (N= 98)		
	Events	Subjs	%[l]	Events	Subjs	%[l]
Serious Adverse Events						
All	79	54	25.7%	30	24	24.5%
Device Related[†]	9	7	3.3%	4	4	4.1%
Device Related - Possibly	8	7	3.3%	3	3	3.1%
Device Related - Probably	0	0	0.0%	0	0	0.0%
Device Related - Definitely	1	1	0.5%	1	1	1.0%
Procedure Related[†]	8	7	3.3%	5	4	4.1%
Procedure Related - Possibly	3	3	1.4%	2	2	2.0%
Procedure Related - Probably	3	2	1.0%	0	0	0.0%
Procedure Related - Definitely	2	2	1.0%	3	2	2.0%
Device or Procedure Related[†]	11	9	4.3%	6	5	5.1%
AE by Severity						
Mild	290	119	56.7%	114	39	39.8%
Moderate	120	62	29.5%	59	31	31.6%
Severe	27	22	10.5%	19	17	17.3%
SAE by Severity						
Mild	27	23	11.0%	7	5	5.1%
Moderate	28	21	10.0%	7	7	7.1%
Severe	24	20	9.5%	16	14	14.3%

[†]Definite, probable, and possible.
[l]Percent values listed reflect the percentage of subjects that experienced the specific type of adverse event (denom inator is sample N noted in the column header).
Source: Tables Safety - AE Summary.sas; Analyzed: 19JUN2026

All Adverse Events

Table 62 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 AT Analysis Set. The investigational group presented with 437 events occurring in 65.7% (138/210) of the 210 BAGUERA® C subjects, compared to 192 events occurring in 59.2% (58/98) of the 98 Mobi-C control subjects.

The most common AEs (rate of 5% or more) included: cervical pain (no narcotic given) (investigational – 19.0%, 40/210; control – 19.4%, 19/98); radiculopathy (including radicular arm pain) (investigational – 16.2%, 34/210; control – 16.3%, 16/98); dysphagia (investigational – 12.9%, 27/210; control – 12.2%, 12/98); numbness and tingling, upper extremity (investigational – 11.0%, 23/210; control – 13.3%, 13/98); lumbar pain (investigational – 10.5%, 22/210; control – 11.2%, 11/98); shoulder pain (investigational – 9.0%, 19/210; control – 11.2%, 11/98); joint pain (investigational – 6.7%, 14/210; control – 5.1%, 5/98).

Table 62 All Adverse Events (AT Analysis Set, N=308)

	BAGUERA® C (N= 210)			Mobi-C (N= 98)			Dif		
	AEs	Subjs	%*	AEs	Subjs	%*	%	LB†	UB†
All	**437**	**138**	**65.7%**	**192**	**58**	**59.2%**	**6.5%**	**-5.1%**	**18.2%**
Blood and Lymphatic System Disorders	**0**	**0**	**0.0%**	**1**	**1**	**1.0%**	**-1.0%**		
Blood Clots (non-pulmonary)	0	0	0.0%	1	1	1.0%	-1.0%		
Cardiac Disorders	**4**	**4**	**1.9%**	**2**	**2**	**2.0%**	**-0.1%**		
Atrial Fibrillation	1	1	0.5%	0	0	0.0%	0.5%		
Chest Pain	1	1	0.5%	0	0	0.0%	0.5%		
Mitral Valve Disease	0	0	0.0%	1	1	1.0%	-1.0%		
Ventricular Arrhythmia	1	1	0.5%	1	1	1.0%	-0.5%		
Aortic Stenosis	1	1	0.5%	0	0	0.0%	0.5%		
Device (non system specific)	**1**	**1**	**0.5%**	**1**	**1**	**1.0%**	**-0.5%**		
Implant Loosening	1	1	0.5%	0	0	0.0%	0.5%		
Implant Migration	0	0	0.0%	1	1	1.0%	-1.0%		
Ear and Labyrinth Disorders	**9**	**8**	**3.8%**	**0**	**0**	**0.0%**	**3.8%**		
Ear Pain	2	2	1.0%	0	0	0.0%	1.0%		
Vertigo	6	6	2.9%	0	0	0.0%	2.9%		
Other Ear and Labyrinth Disorders	1	1	0.5%	0	0	0.0%	0.5%		
Endocrine Disorders	**3**	**3**	**1.4%**	**0**	**0**	**0.0%**	**1.4%**		
Diabetes Mellitus	1	1	0.5%	0	0	0.0%	0.5%		
Hypothyroidism	2	2	1.0%	0	0	0.0%	1.0%		
Eye Disorders	**4**	**4**	**1.9%**	**1**	**1**	**1.0%**	**0.9%**		
Blurred Vision	1	1	0.5%	1	1	1.0%	-0.5%		
Retinal Detachment	1	1	0.5%	0	0	0.0%	0.5%		
Retinopathy	1	1	0.5%	0	0	0.0%	0.5%		
Other Eye Disorders	1	1	0.5%	0	0	0.0%	0.5%		
Gastrointestinal Disorders	**40**	**36**	**17.1%**	**16**	**15**	**15.3%**	**1.8%**	**-6.9%**	**10.6%**
Colitis	1	1	0.5%	0	0	0.0%	0.5%		
Constipation	1	1	0.5%	1	1	1.0%	-0.5%		
Dysphagia	28	27	12.9%	12	12	12.2%	0.6%	-7.3%	8.5%
Gastroesophageal Reflux Disease	1	1	0.5%	1	1	1.0%	-0.5%		
Nausea	2	2	1.0%	0	0	0.0%	1.0%		
Obstruction, Specify Location	1	1	0.5%	1	1	1.0%	-0.5%		
Pancreatitis	1	1	0.5%	0	0	0.0%	0.5%		
Eructation	1	1	0.5%	0	0	0.0%	0.5%		
Other Gastrointestinal Disorder	4	4	1.9%	1	1	1.0%	0.9%		
General Disorders and Administrative Site Conditions	**5**	**5**	**2.4%**	**1**	**1**	**1.0%**	**1.4%**		
Fever	0	0	0.0%	1	1	1.0%	-1.0%		
General Pain, Not Specified Elsewhere	1	1	0.5%	0	0	0.0%	0.5%		
Hernia	2	2	1.0%	0	0	0.0%	1.0%		
Inflammatory condition	1	1	0.5%	0	0	0.0%	0.5%		
Incision Site Tenderness	1	1	0.5%	0	0	0.0%	0.5%		
Hepatobiliary Disorders	**1**	**1**	**0.5%**	**0**	**0**	**0.0%**	**0.5%**		
Gallbladder Pain	1	1	0.5%	0	0	0.0%	0.5%		
Immune System Disorders	**2**	**2**	**1.0%**	**1**	**1**	**1.0%**	**-0.1%**		
Allergic Reaction	1	1	0.5%	0	0	0.0%	0.5%		
Foreign Body Reaction, Implant Material	0	0	0.0%	1	1	1.0%	-1.0%		

	BAGUERA® C (N= 210)			Mobi-C (N= 98)			Dif		
	AEs	Subjs	%*	AEs	Subjs	%*	%	LB†	UB†
Inflammatory Condition	1	1	0.5%	0	0	0.0%	0.5%		
Infections and Infestations	**18**	**13**	**6.2%**	**8**	**4**	**4.1%**	**2.1%**		
Appendicitis	1	1	0.5%	1	1	1.0%	-0.5%		
Infection, Not at Surgical Site	1	1	0.5%	0	0	0.0%	0.5%		
Sinusitis	1	1	0.5%	2	2	2.0%	-1.6%		
COVID-19 Infection	5	4	1.9%	0	0	0.0%	1.9%		
Abscess, Oral	1	1	0.5%	0	0	0.0%	0.5%		
Herpes zoster	3	3	1.4%	1	1	1.0%	0.4%		
Respiratory Tract Infection	1	1	0.5%	2	2	2.0%	-1.6%		
Urinary Tract Infection	2	2	1.0%	2	1	1.0%	-0.1%		
Oropharyngeal Infection	1	1	0.5%	0	0	0.0%	0.5%		
Other Infections and Infestations	2	2	1.0%	0	0	0.0%	1.0%		
Metabolism and Nutrition Disorders	**3**	**3**	**1.4%**	**1**	**1**	**1.0%**	**0.4%**		
Dehydration	1	1	0.5%	1	1	1.0%	-0.5%		
Hyperlipidemia	2	2	1.0%	0	0	0.0%	1.0%		
Musculoskeletal and Connective Tissue Disorders	**172**	**95**	**45.2%**	**76**	**36**	**36.7%**	**8.5%**	**-3.2%**	**20.2%**
Arm Pain (not radicular)	4	4	1.9%	5	4	4.1%	-2.2%		
Cervical pain (no narcotic given)	43	40	19.0%	20	19	19.4%	-0.3%	-9.8%	9.1%
Cervical pain (narcotic given)	5	5	2.4%	1	1	1.0%	1.4%		
Joint pain	17	14	6.7%	6	5	5.1%	1.6%	-3.9%	7.1%
Joint stiffness	2	1	0.5%	1	1	1.0%	-0.5%		
Lumbar pain	22	22	10.5%	11	11	11.2%	-0.7%	-8.2%	6.7%
Neck stiffness	7	6	2.9%	3	3	3.1%	-0.2%		
Other Musculoskeletal Pain, Specify Location	8	4	1.9%	3	2	2.0%	-0.1%		
Spasms	4	4	1.9%	4	4	4.1%	-2.2%		
Sprain	2	2	1.0%	0	0	0.0%	1.0%		
Cervical Foraminal Stenosis	1	1	0.5%	0	0	0.0%	0.5%		
Lumbar Spinal Stenosis	3	3	1.4%	2	2	2.0%	-0.6%		
Muscle Rupture	1	1	0.5%	0	0	0.0%	0.5%		
Muscle Strain	2	2	1.0%	0	0	0.0%	1.0%		
Muscle Tension	5	5	2.4%	0	0	0.0%	2.4%		
Osteoarthritis	5	4	1.9%	1	1	1.0%	0.9%		
Shoulder Blade Pain	4	4	1.9%	4	4	4.1%	-2.2%		
Shoulder Pain	20	19	9.0%	11	11	11.2%	-2.2%	-9.5%	5.2%
Thoracic Pain	5	5	2.4%	1	1	1.0%	1.4%		
Trapezius Pain	2	2	1.0%	2	2	2.0%	-1.1%		
Trigger Finger	1	1	0.5%	0	0	0.0%	0.5%		
Fracture, Any Bone	8	8	3.8%	0	0	0.0%	3.8%		
Other Musculoskeletal and Connective Tissue Disorder	1	1	0.5%	1	1	1.0%	-0.5%		
Nervous System Disorders	**117**	**69**	**32.9%**	**57**	**35**	**35.7%**	**-2.9%**	**-14.3%**	**8.6%**
Cognitive disturbance	1	1	0.5%	0	0	0.0%	0.5%		
Compressive neuropathy	10	6	2.9%	3	3	3.1%	-0.2%		
Coordination abnormalities	4	3	1.4%	0	0	0.0%	1.4%		
Dizziness	2	2	1.0%	3	2	2.0%	-1.1%		
Headache	7	7	3.3%	7	7	7.1%	-3.8%	-9.5%	1.8%
Neuralgia	1	1	0.5%	0	0	0.0%	0.5%		
Numbness/tingling	2	2	1.0%	1	1	1.0%	-0.1%		
Paresthesia	1	1	0.5%	1	1	1.0%	-0.5%		

	BAGUERA® C (N= 210)			Mobi-C (N= 98)			Dif		
	AEs	Subjs	%*	AEs	Subjs	%*	%	LB†	UB†
Radiculopathy (including radicular arm pain)	41	34	16.2%	17	16	16.3%	-0.1%	-9.0%	8.7%
Temporary or permanent nerve damage	1	1	0.5%	0	0	0.0%	0.5%		
Weakness	6	5	2.4%	2	2	2.0%	0.3%		
Mononeuropathy	0	0	0.0%	1	1	1.0%	-1.0%		
Numbness/Tingling, Upper Extremity	30	23	11.0%	18	13	13.3%	-2.3%	-10.2%	5.6%
Numbness/Tingling, Lower Extremity	8	6	2.9%	0	0	0.0%	2.9%		
Peripheral Neuropathy	2	2	1.0%	4	3	3.1%	-2.1%		
Other nervous system disorder	1	1	0.5%	0	0	0.0%	0.5%		
Psychiatric Disorders	**4**	**3**	**1.4%**	**3**	**3**	**3.1%**	**-1.6%**		
Anxiety Disorders	0	0	0.0%	1	1	1.0%	-1.0%		
Depression	2	2	1.0%	0	0	0.0%	1.0%		
Insomnia	1	1	0.5%	2	2	2.0%	-1.6%		
Other Psychiatric Disorder	1	1	0.5%	0	0	0.0%	0.5%		
Renal and Urinary Disorders	**12**	**11**	**5.2%**	**2**	**2**	**2.0%**	**3.2%**		
Renal Calculi	8	7	3.3%	1	1	1.0%	2.3%		
Urinary Retention	0	0	0.0%	1	1	1.0%	-1.0%		
Urinary Hesitancy	1	1	0.5%	0	0	0.0%	0.5%		
Other Renal and Urinary Disorder	3	3	1.4%	0	0	0.0%	1.4%		
Reproductive System and Breast Disorders	**1**	**1**	**0.5%**	**1**	**1**	**1.0%**	**-0.5%**		
Breast Neoplasm	1	1	0.5%	0	0	0.0%	0.5%		
Other Reproductive System and Breast Disorder	0	0	0.0%	1	1	1.0%	-1.0%		
Respiratory, Thoracic and Mediastinal Disorders	**18**	**17**	**8.1%**	**5**	**5**	**5.1%**	**3.0%**	**-2.7%**	**8.7%**
Allergic Rhinitis	1	1	0.5%	0	0	0.0%	0.5%		
Asthma	2	2	1.0%	0	0	0.0%	1.0%		
Cough	2	2	1.0%	0	0	0.0%	1.0%		
Dysphonia	3	3	1.4%	2	2	2.0%	-0.6%		
Dyspnea	1	1	0.5%	0	0	0.0%	0.5%		
Hoarseness	3	3	1.4%	0	0	0.0%	1.4%		
Nasal congestion	0	0	0.0%	1	1	1.0%	-1.0%		
Sleep apnea	1	1	0.5%	1	1	1.0%	-0.5%		
Sore throat	2	2	1.0%	0	0	0.0%	1.0%		
Pulmonary embolism	1	1	0.5%	0	0	0.0%	0.5%		
Airway obstruction	0	0	0.0%	1	1	1.0%	-1.0%		
Other Respiratory, Thoracic and Mediastinal Disorders Disorder	2	2	1.0%	0	0	0.0%	1.0%		
Skin and Subcutaneous Tissue Disorders	**10**	**9**	**4.3%**	**5**	**5**	**5.1%**	**-0.8%**	**-6.0%**	**4.3%**
Cyst	3	3	1.4%	2	2	2.0%	-0.6%		
Hematoma	0	0	0.0%	1	1	1.0%	-1.0%		
Urticaria	2	2	1.0%	0	0	0.0%	1.0%		
Wound complications (eg., dehiscence, bruising) and soft tissue damage	3	3	1.4%	0	0	0.0%	1.4%		
Wound secretions / drainage	0	0	0.0%	1	1	1.0%	-1.0%		
Other Skin and Subcutaneous Tissue Disorder	2	2	1.0%	1	1	1.0%	-0.1%		

	BAGUERA® C (N= 210)			Mobi-C (N= 98)			Dif		
	AEs	Subjs	%*	AEs	Subjs	%*	%	LB†	UB†
Vascular Disorders	**3**	**3**	**1.4%**	**3**	**3**	**3.1%**	**-1.6%**		
Angioedema	1	1	0.5%	1	1	1.0%	-0.5%		
Hypertension	1	1	0.5%	1	1	1.0%	-0.5%		
Transient Ischaemic Attack	0	0	0.0%	1	1	1.0%	-1.0%		
Other Vascular Disorder	1	1	0.5%	0	0	0.0%	0.5%		
Other Complications/Events	**10**	**10**	**4.8%**	**8**	**6**	**6.1%**	**-1.4%**	**-6.9%**	**4.2%**
Cancer	4	4	1.9%	3	3	3.1%	-1.2%		
Adverse Reaction to Anesthesia	1	1	0.5%	0	0	0.0%	0.5%		
Other Event, Describe	1	1	0.5%	1	1	1.0%	-0.5%		
Accident and injury	4	4	1.9%	3	1	1.0%	0.9%		
Odynophagia	0	0	0.0%	1	1	1.0%	-1.0%		

*Percentage of subjects experiencing specific event.
† 95% Asymptotic CI reported when at least five subjects experienced the AE and at least five subjects did not experience the AE.
Source: Tables Safety.sas; Analyzed: 19JUN2026

All Adverse Events by Time Course

Table 63 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 1 and Month 3 for the control group.

Table 63 All Adverse Events (Time course) – AT Analysis Set N=308

	Days Post-Op															
	<0		0-2		2-30		30-90		90-180		180-365		365-730		Total	
	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C
All	**0**	**0**	**36**	**17**	**46**	**25**	**66**	**49**	**65**	**23**	**94**	**43**	**130**	**35**	**437**	**192**
Blood and Lymphatic System Disorders	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**1**
Blood Clots (non-pulmonary)	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1
Cardiac Disorders	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**1**	**1**	**1**	**0**	**2**	**0**	**4**	**2**
Atrial Fibrillation	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0
Chest Pain	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1	0
Mitral Valve Disease	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1
Ventricular Arrhythmia	0	0	0	0	0	0	0	0	0	1	1	0	0	0	1	1
Aortic Stenosis	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0
Device (non system specific)	**0**	**0**	**0**	**1**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**1**	**1**
Implant Loosening	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0
Implant Migration	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1
Ear and Labyrinth Disorders	**0**	**0**	**0**	**0**	**2**	**0**	**1**	**0**	**0**	**0**	**4**	**0**	**2**	**0**	**9**	**0**
Ear Pain	0	0	0	0	0	0	0	0	0	0	0	0	2	0	2	0
Vertigo	0	0	0	0	1	0	1	0	0	0	4	0	0	0	6	0
Other Ear and Labyrinth Disorders	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1	0
Endocrine Disorders	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**2**	**0**	**1**	**0**	**3**	**0**
Diabetes Mellitus	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0
Hypothyroidism	0	0	0	0	0	0	0	0	0	0	2	0	0	0	2	0
Eye Disorders	**0**	**0**	**1**	**0**	**1**	**0**	**1**	**1**	**1**	**0**	**0**	**0**	**0**	**0**	**4**	**1**
Blurred Vision	0	0	0	0	0	0	1	1	0	0	0	0	0	0	1	1
Retinal Detachment	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1	0
Retinopathy	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1	0
Other Eye Disorders	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1	0
Gastrointestinal Disorders	**0**	**0**	**21**	**7**	**2**	**2**	**6**	**4**	**3**	**0**	**1**	**0**	**7**	**3**	**40**	**16**
Colitis	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0
Constipation	0	0	0	0	0	1	0	0	0	0	0	0	1	0	1	1
Dysphagia	0	0	18	7	1	1	5	4	2	0	0	0	2	0	28	12
Gastroesophageal Reflux Disease	0	0	0	0	0	0	0	0	0	0	1	0	0	1	1	1
Nausea	0	0	1	0	0	0	0	0	0	0	0	0	1	0	2	0
Obstruction, Specify Location	0	0	0	0	0	0	0	0	0	0	0	0	1	1	1	1
Pancreatitis	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1	0
Eructation	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1	0
Other Gastrointestinal Disorder	0	0	1	0	0	0	1	0	1	0	0	0	1	1	4	1

	Days Post-Op															
	<0		0-2		2-30		30-90		90-180		180-365		365-730		Total	
	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C
General Disorders and Administrative Site Conditions	**0**	**0**	**0**	**0**	**1**	**1**	**3**	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**5**	**1**
Fever	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1
General Pain, Not Specified Elsewhere	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	0
Hernia	0	0	0	0	0	0	1	0	0	0	0	0	1	0	2	0
Inflammatory condition	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	0
Incision Site Tenderness	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1	0
Hepatobiliary Disorders	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**0**	**0**	**1**	**0**
Gallbladder Pain	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0
Immune System Disorders	**0**	**0**	**0**	**0**	**1**	**0**	**0**	**0**	**0**	**1**	**0**	**0**	**1**	**0**	**2**	**1**
Allergic Reaction	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1	0
Foreign Body Reaction, Implant Material	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1
Inflammatory Condition	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0
Infections and Infestations	**0**	**0**	**1**	**0**	**3**	**0**	**2**	**1**	**5**	**2**	**5**	**2**	**2**	**3**	**18**	**8**
Appendicitis	0	0	0	0	0	0	0	0	1	1	0	0	0	0	1	1
Infection, Not at Surgical Site	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1	0
Sinusitis	0	0	0	0	0	0	0	0	0	0	0	1	1	1	1	2
COVID-19 Infection	0	0	0	0	0	0	2	0	1	0	1	0	1	0	5	0
Abscess, Oral	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0
Herpes zoster	0	0	1	0	0	0	0	0	2	0	0	1	0	0	3	1
Respiratory Tract Infection	0	0	0	0	0	0	0	0	0	1	1	0	0	1	1	2
Urinary Tract Infection	0	0	0	0	1	0	0	1	0	0	1	0	0	1	2	2
Oropharyngeal Infection	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1	0
Other Infections and Infestations	0	0	0	0	0	0	0	0	1	0	1	0	0	0	2	0
Metabolism and Nutrition Disorders	**0**	**0**	**0**	**0**	**1**	**1**	**2**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**3**	**1**
Dehydration	0	0	0	0	0	1	1	0	0	0	0	0	0	0	1	1
Hyperlipidemia	0	0	0	0	1	0	1	0	0	0	0	0	0	0	2	0
Musculoskeletal and Connective Tissue Disorders	**0**	**0**	**5**	**5**	**20**	**8**	**28**	**18**	**29**	**9**	**43**	**23**	**47**	**13**	**172**	**76**
Arm Pain (not radicular)	0	0	0	1	0	2	1	0	1	0	1	2	1	0	4	5
Cervical pain (no narcotic given)	0	0	3	2	8	2	6	5	8	2	9	7	9	2	43	20
Cervical pain (narcotic given)	0	0	1	0	1	0	0	1	1	0	1	0	1	0	5	1
Joint pain	0	0	0	0	1	0	5	2	1	1	2	3	8	0	17	6
Joint stiffness	0	0	0	0	0	0	0	0	1	0	1	1	0	0	2	1
Lumbar pain	0	0	0	0	3	0	3	2	5	3	6	4	5	2	22	11

	Days Post-Op															
	<0		0-2		2-30		30-90		90-180		180-365		365-730		Total	
	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C
Neck stiffness	0	0	0	0	1	0	1	1	0	1	3	1	2	0	7	3
Other Musculoskeletal Pain, Specify Location	0	0	0	0	0	0	1	0	1	0	2	0	4	3	8	3
Spasms	0	0	0	1	0	0	1	1	1	0	1	1	1	1	4	4
Sprain	0	0	0	0	0	0	1	0	1	0	0	0	0	0	2	0
Cervical Foraminal Stenosis	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1	0
Lumbar Spinal Stenosis	0	0	0	0	0	0	0	1	0	0	2	1	1	0	3	2
Muscle Rupture	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0
Muscle Strain	0	0	0	0	0	0	1	0	0	0	1	0	0	0	2	0
Muscle Tension	0	0	0	0	1	0	3	0	1	0	0	0	0	0	5	0
Osteoarthritis	0	0	0	0	0	0	0	1	2	0	0	0	3	0	5	1
Shoulder Blade Pain	0	0	1	0	1	1	1	1	0	0	0	1	1	1	4	4
Shoulder Pain	0	0	0	0	1	2	3	3	3	1	5	2	8	3	20	11
Thoracic Pain	0	0	0	0	1	0	1	0	2	1	0	0	1	0	5	1
Trapezius Pain	0	0	0	1	0	1	0	0	0	0	2	0	0	0	2	2
Trigger Finger	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0
Fracture, Any Bone	0	0	0	0	1	0	0	0	1	0	6	0	0	0	8	0
Other Musculoskeletal and Connective Tissue Disorder	0	0	0	0	0	0	0	0	0	0	0	0	1	1	1	1
Nervous System Disorders	**0**	**0**	**1**	**0**	**7**	**8**	**20**	**20**	**19**	**7**	**29**	**11**	**41**	**11**	**117**	**57**
Cognitive disturbance	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0
Compressive neuropathy	0	0	0	0	0	0	1	0	0	1	1	1	8	1	10	3
Coordination abnormalities	0	0	0	0	0	0	2	0	0	0	0	0	2	0	4	0
Dizziness	0	0	0	0	1	0	0	2	0	0	0	1	1	0	2	3
Headache	0	0	0	0	0	1	2	2	1	1	2	1	2	2	7	7
Neuralgia	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0
numbness/tingling	0	0	0	0	2	1	0	0	0	0	0	0	0	0	2	1
Paresthesia	0	0	0	0	0	0	0	0	1	0	0	0	0	1	1	1
Radiculopathy (including radicular arm pain)	0	0	0	0	2	1	3	4	10	2	11	6	15	4	41	17
Temporary or permanent nerve damage	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1	0
Weakness	0	0	0	0	1	0	1	1	0	0	0	0	4	1	6	2
Mononeuropathy	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1
Numbness/Tingling, Upper Extremity	0	0	0	0	1	4	7	8	6	2	10	2	6	2	30	18
Numbness/Tingling, Lower Extremity	0	0	0	0	0	0	3	0	0	0	4	0	1	0	8	0
Peripheral Neuropathy	0	0	0	0	0	0	1	3	1	1	0	0	0	0	2	4

	Days Post-Op															
	<0		0-2		2-30		30-90		90-180		180-365		365-730		Total	
	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C
Other nervous system disorder	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0
Psychiatric Disorders	**0**	**0**	**0**	**0**	**1**	**0**	**0**	**0**	**1**	**0**	**1**	**1**	**1**	**2**	**4**	**3**
Anxiety Disorders	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1
Depression	0	0	0	0	0	0	0	0	1	0	1	0	0	0	2	0
Insomnia	0	0	0	0	1	0	0	0	0	0	0	1	0	1	1	2
Other Psychiatric Disorder	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0
Renal and Urinary Disorders	**0**	**0**	**1**	**0**	**0**	**1**	**0**	**1**	**1**	**0**	**2**	**0**	**8**	**0**	**12**	**2**
Renal Calculi	0	0	1	0	0	0	0	1	1	0	2	0	4	0	8	1
Urinary Retention	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1
Urinary Hesitancy	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0
Other Renal and Urinary Disorder	0	0	0	0	0	0	0	0	0	0	0	0	3	0	3	0
Respiratory, Thoracic and Mediastinal Disorders	**0**	**0**	**5**	**3**	**3**	**0**	**1**	**1**	**1**	**0**	**1**	**1**	**7**	**0**	**18**	**5**
Allergic Rhinitis	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0
Asthma	0	0	0	0	0	0	0	0	1	0	0	0	1	0	2	0
Cough	0	0	0	0	2	0	0	0	0	0	0	0	0	0	2	0
Dysphonia	0	0	2	2	1	0	0	0	0	0	0	0	0	0	3	2
Dyspnea	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	0
Hoarseness	0	0	3	0	0	0	0	0	0	0	0	0	0	0	3	0
Nasal congestion	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1
Sleep apnea	0	0	0	0	0	0	0	0	0	0	0	1	1	0	1	1
Sore throat	0	0	0	0	0	0	0	0	0	0	1	0	1	0	2	0
Pulmonary embolism	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0
Airway obstruction	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1
Other Respiratory, Thoracic and Mediastinal Disorders Disorder	0	0	0	0	0	0	0	0	0	0	0	0	2	0	2	0
Skin and Subcutaneous Tissue Disorders	**0**	**0**	**0**	**0**	**4**	**1**	**2**	**2**	**2**	**0**	**0**	**2**	**2**	**0**	**10**	**5**
Cyst	0	0	0	0	0	0	2	1	0	0	0	1	1	0	3	2
Hematoma	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1
Urticaria	0	0	0	0	1	0	0	0	1	0	0	0	0	0	2	0
Wound complications (eg., dehiscence, bruising) and soft tissue damage	0	0	0	0	3	0	0	0	0	0	0	0	0	0	3	0
Wound secretions / drainage	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1

	Days Post-Op															
	<0		0-2		2-30		30-90		90-180		180-365		365-730		Total	
	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C
Other Skin and Subcutaneous Tissue Disorder	0	0	0	0	0	0	0	0	1	0	0	1	1	0	2	1
Vascular Disorders	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**0**	**1**	**1**	**0**	**0**	**2**	**1**	**3**	**3**
Angioedema	0	0	0	0	0	1	0	0	1	0	0	0	0	0	1	1
Hypertension	0	0	0	0	0	0	0	0	0	0	0	0	1	1	1	1
Transient Ischaemic Attack	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1
Other Vascular Disorder	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0
Other Complications/Events	**0**	**0**	**1**	**1**	**0**	**0**	**0**	**0**	**1**	**2**	**3**	**3**	**5**	**2**	**10**	**8**
Cancer	0	0	0	0	0	0	0	0	0	0	1	1	3	2	4	3
Adverse Reaction to Anesthesia	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1	0
Other Event, Describe	0	0	0	1	0	0	0	0	0	0	0	0	1	0	1	1
Accident and injury	0	0	0	0	0	0	0	0	1	2	2	1	1	0	4	3
Odynophagia	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1

Source: Tables Safety.sas; Analyzed: 19JUN2026

All Adverse Events by Severity

Table 64 presents the AEs observed in the investigational group stratified by severity. These AEs were classified as Mild, Moderate, or Severe events. Overall, there were 290 mild AEs, 120 moderate AEs, and 27 Severe AEs reported in the BAGUERA® C group in the AT population (n=210).

Table 64 All Adverse Events (Severity) – BAGUERA® C Investigational (AT Analysis Set, N=210)

	Mild		Moderate		Severe		Total
	Events	%*	Events	%*	Events	%*	Events
All	**290**	**66.4%**	**120**	**27.5%**	**27**	**6.2%**	**437**
Cardiac Disorders	**2**	**50.0%**	**1**	**25.0%**	**1**	**25.0%**	**4**
Atrial Fibrillation	1	100.0%	0	0.0%	0	0.0%	1
Chest Pain	1	100.0%	0	0.0%	0	0.0%	1
Ventricular Arrhythmia	0	0.0%	1	100.0%	0	0.0%	1
Aortic Stenosis	0	0.0%	0	0.0%	1	100.0%	1
Device (non system specific)	**0**	**0.0%**	**0**	**0.0%**	**1**	**100.0%**	**1**
Implant Loosening	0	0.0%	0	0.0%	1	100.0%	1
Ear and Labyrinth Disorders	**8**	**88.9%**	**1**	**11.1%**	**0**	**0.0%**	**9**
Ear Pain	2	100.0%	0	0.0%	0	0.0%	2
Vertigo	5	83.3%	1	16.7%	0	0.0%	6
Other Ear and Labyrinth Disorders	1	100.0%	0	0.0%	0	0.0%	1
Endocrine Disorders	**2**	**66.7%**	**1**	**33.3%**	**0**	**0.0%**	**3**
Diabetes Mellitus	1	100.0%	0	0.0%	0	0.0%	1
Hypothyroidism	1	50.0%	1	50.0%	0	0.0%	2
Eye Disorders	**3**	**75.0%**	**0**	**0.0%**	**1**	**25.0%**	**4**
Blurred Vision	1	100.0%	0	0.0%	0	0.0%	1
Retinal Detachment	0	0.0%	0	0.0%	1	100.0%	1
Retinopathy	1	100.0%	0	0.0%	0	0.0%	1
Other Eye Disorders	1	100.0%	0	0.0%	0	0.0%	1
Gastrointestinal Disorders	**28**	**70.0%**	**8**	**20.0%**	**4**	**10.0%**	**40**
Colitis	1	100.0%	0	0.0%	0	0.0%	1
Constipation	1	100.0%	0	0.0%	0	0.0%	1
Dysphagia	23	82.1%	5	17.9%	0	0.0%	28
Gastroesophageal Reflux Disease	0	0.0%	1	100.0%	0	0.0%	1
Nausea	1	50.0%	0	0.0%	1	50.0%	2
Obstruction, Specify Location	0	0.0%	0	0.0%	1	100.0%	1
Pancreatitis	0	0.0%	1	100.0%	0	0.0%	1
Eructation	1	100.0%	0	0.0%	0	0.0%	1
Other Gastrointestinal Disorder	1	25.0%	1	25.0%	2	50.0%	4
General Disorders and Administrative Site Conditions	**3**	**60.0%**	**1**	**20.0%**	**1**	**20.0%**	**5**
General Pain, Not Specified Elsewhere	0	0.0%	1	100.0%	0	0.0%	1
Hernia	1	50.0%	0	0.0%	1	50.0%	2

	Mild		Moderate		Severe		Total
	Events	%*	Events	%*	Events	%*	Events
Inflammatory condition	1	100.0%	0	0.0%	0	0.0%	1
Incision Site Tenderness	1	100.0%	0	0.0%	0	0.0%	1
Hepatobiliary Disorders	**1**	**100.0%**	**0**	**0.0%**	**0**	**0.0%**	**1**
Gallbladder Pain	1	100.0%	0	0.0%	0	0.0%	1
Immune System Disorders	**1**	**50.0%**	**1**	**50.0%**	**0**	**0.0%**	**2**
Allergic Reaction	1	100.0%	0	0.0%	0	0.0%	1
Inflammatory Condition	0	0.0%	1	100.0%	0	0.0%	1
Infections and Infestations	**12**	**66.7%**	**4**	**22.2%**	**2**	**11.1%**	**18**
Appendicitis	0	0.0%	0	0.0%	1	100.0%	1
Infection, Not at Surgical Site	0	0.0%	1	100.0%	0	0.0%	1
Sinusitis	1	100.0%	0	0.0%	0	0.0%	1
COVID-19 Infection	5	100.0%	0	0.0%	0	0.0%	5
Abscess, Oral	1	100.0%	0	0.0%	0	0.0%	1
Herpes zoster	2	66.7%	0	0.0%	1	33.3%	3
Respiratory Tract Infection	0	0.0%	1	100.0%	0	0.0%	1
Urinary Tract Infection	1	50.0%	1	50.0%	0	0.0%	2
Oropharyngeal Infection	0	0.0%	1	100.0%	0	0.0%	1
Other Infections and Infestations	2	100.0%	0	0.0%	0	0.0%	2
Metabolism and Nutrition Disorders	**2**	**66.7%**	**1**	**33.3%**	**0**	**0.0%**	**3**
Dehydration	1	100.0%	0	0.0%	0	0.0%	1
Hyperlipidemia	1	50.0%	1	50.0%	0	0.0%	2
Musculoskeletal and Connective Tissue Disorders	**117**	**68.0%**	**48**	**27.9%**	**7**	**4.1%**	**172**
Arm Pain (not radicular)	3	75.0%	1	25.0%	0	0.0%	4
Cervical pain (no narcotic given)	34	79.1%	9	20.9%	0	0.0%	43
Cervical pain (narcotic given)	4	80.0%	1	20.0%	0	0.0%	5
Joint pain	8	47.1%	8	47.1%	1	5.9%	17
Joint stiffness	2	100.0%	0	0.0%	0	0.0%	2
Lumbar pain	13	59.1%	8	36.4%	1	4.5%	22
Neck stiffness	7	100.0%	0	0.0%	0	0.0%	7
Other Musculoskeletal Pain, Specify Location	6	75.0%	2	25.0%	0	0.0%	8
Spasms	2	50.0%	2	50.0%	0	0.0%	4
Sprain	2	100.0%	0	0.0%	0	0.0%	2
Cervical Foraminal Stenosis	0	0.0%	0	0.0%	1	100.0%	1
Lumbar Spinal Stenosis	1	33.3%	1	33.3%	1	33.3%	3
Muscle Rupture	0	0.0%	1	100.0%	0	0.0%	1
Muscle Strain	1	50.0%	1	50.0%	0	0.0%	2
Muscle Tension	5	100.0%	0	0.0%	0	0.0%	5
Osteoarthritis	3	60.0%	2	40.0%	0	0.0%	5
Shoulder Blade Pain	3	75.0%	1	25.0%	0	0.0%	4
Shoulder Pain	13	65.0%	4	20.0%	3	15.0%	20
Thoracic Pain	3	60.0%	2	40.0%	0	0.0%	5
Trapezius Pain	2	100.0%	0	0.0%	0	0.0%	2
Trigger Finger	1	100.0%	0	0.0%	0	0.0%	1

	Mild		Moderate		Severe		Total
	Events	%*	Events	%*	Events	%*	Events
Fracture, Any Bone	4	50.0%	4	50.0%	0	0.0%	8
Other Musculoskeletal and Connective Tissue Disorder	0	0.0%	1	100.0%	0	0.0%	1
Nervous System Disorders	**75**	**64.1%**	**37**	**31.6%**	**5**	**4.3%**	**117**
Cognitive disturbance	1	100.0%	0	0.0%	0	0.0%	1
Compressive neuropathy	5	50.0%	5	50.0%	0	0.0%	10
Coordination abnormalities	1	25.0%	3	75.0%	0	0.0%	4
Dizziness	1	50.0%	1	50.0%	0	0.0%	2
Headache	6	85.7%	1	14.3%	0	0.0%	7
Neuralgia	0	0.0%	1	100.0%	0	0.0%	1
numbness/tingling	2	100.0%	0	0.0%	0	0.0%	2
Paresthesia	1	100.0%	0	0.0%	0	0.0%	1
Radiculopathy (including radicular arm pain)	24	58.5%	13	31.7%	4	9.8%	41
Temporary or permanent nerve damage	1	100.0%	0	0.0%	0	0.0%	1
Weakness	3	50.0%	2	33.3%	1	16.7%	6
Numbness/Tingling, Upper Extremity	22	73.3%	8	26.7%	0	0.0%	30
Numbness/Tingling, Lower Extremity	8	100.0%	0	0.0%	0	0.0%	8
Peripheral Neuropathy	0	0.0%	2	100.0%	0	0.0%	2
Other nervous system disorder	0	0.0%	1	100.0%	0	0.0%	1
Psychiatric Disorders	**2**	**50.0%**	**2**	**50.0%**	**0**	**0.0%**	**4**
Depression	1	50.0%	1	50.0%	0	0.0%	2
Insomnia	1	100.0%	0	0.0%	0	0.0%	1
Other Psychiatric Disorder	0	0.0%	1	100.0%	0	0.0%	1
Renal and Urinary Disorders	**4**	**33.3%**	**6**	**50.0%**	**2**	**16.7%**	**12**
Renal Calculi	3	37.5%	3	37.5%	2	25.0%	8
Urinary Hesitancy	0	0.0%	1	100.0%	0	0.0%	1
Other Renal and Urinary Disorder	1	33.3%	2	66.7%	0	0.0%	3
Reproductive System and Breast Disorders	**0**	**0.0%**	**1**	**100.0%**	**0**	**0.0%**	**1**
Breast Neoplasm	0	0.0%	1	100.0%	0	0.0%	1
Respiratory, Thoracic and Mediastinal Disorders	**17**	**94.4%**	**1**	**5.6%**	**0**	**0.0%**	**18**
Allergic Rhinitis	0	0.0%	1	100.0%	0	0.0%	1
Asthma	2	100.0%	0	0.0%	0	0.0%	2
Cough	2	100.0%	0	0.0%	0	0.0%	2
Dysphonia	3	100.0%	0	0.0%	0	0.0%	3
Dyspnea	1	100.0%	0	0.0%	0	0.0%	1
Hoarseness	3	100.0%	0	0.0%	0	0.0%	3
Sleep apnea	1	100.0%	0	0.0%	0	0.0%	1
Sore throat	2	100.0%	0	0.0%	0	0.0%	2
Pulmonary embolism	1	100.0%	0	0.0%	0	0.0%	1
Other Respiratory, Thoracic and Mediastinal Disorders Disorder	2	100.0%	0	0.0%	0	0.0%	2

	Mild		Moderate		Severe		Total
	Events	%*	Events	%*	Events	%*	Events
Skin and Subcutaneous Tissue Disorders	**6**	**60.0%**	**4**	**40.0%**	**0**	**0.0%**	**10**
Cyst	3	100.0%	0	0.0%	0	0.0%	3
Urticaria	1	50.0%	1	50.0%	0	0.0%	2
Wound complications (eg., dehiscence, bruising) and soft tissue damage	1	33.3%	2	66.7%	0	0.0%	3
Other Skin and Subcutaneous Tissue Disorder	1	50.0%	1	50.0%	0	0.0%	2
Vascular Disorders	**3**	**100.0%**	**0**	**0.0%**	**0**	**0.0%**	**3**
Angioedema	1	100.0%	0	0.0%	0	0.0%	1
Hypertension	1	100.0%	0	0.0%	0	0.0%	1
Other Vascular Disorder	1	100.0%	0	0.0%	0	0.0%	1
Other Complications/Events	**4**	**40.0%**	**3**	**30.0%**	**3**	**30.0%**	**10**
Cancer	1	25.0%	0	0.0%	3	75.0%	4
Adverse Reaction to Anesthesia	0	0.0%	1	100.0%	0	0.0%	1
Other Event, Describe	0	0.0%	1	100.0%	0	0.0%	1
Accident and injury	3	75.0%	1	25.0%	0	0.0%	4

*Percentage of total events for that specific AE code. Row percentages will sum to 100%.
Source: Tables Safety.sas; Analyzed: 19JUN2026

Table 65 presents the AEs observed in the control group stratified by severity. These AEs were classified as Mild, Moderate, or Severe events. Overall, there were 114 mild AEs, 59 moderate AEs, and 19 Severe AEs reported in the Mobi-C control group in the AT population (N=98).

Table 65 All Adverse Events (Severity) – Mobi-C control (AT Analysis Set, N=98)

	Mild		Moderate		Severe		Total
	Events	%*	Events	%*	Events	%*	Events
All	**114**	**59.4%**	**59**	**30.7%**	**19**	**9.9%**	**192**
Blood and Lymphatic System Disorders	**1**	**100.0%**	**0**	**0.0%**	**0**	**0.0%**	**1**
Blood Clots (non-pulmonary)	1	100.0%	0	0.0%	0	0.0%	1
Cardiac Disorders	**1**	**50.0%**	**0**	**0.0%**	**1**	**50.0%**	**2**
Mitral Valve Disease	0	0.0%	0	0.0%	1	100.0%	1
Ventricular Arrhythmia	1	100.0%	0	0.0%	0	0.0%	1
Device (non system specific)	**0**	**0.0%**	**0**	**0.0%**	**1**	**100.0%**	**1**
Implant Migration	0	0.0%	0	0.0%	1	100.0%	1
Eye Disorders	**1**	**100.0%**	**0**	**0.0%**	**0**	**0.0%**	**1**
Blurred Vision	1	100.0%	0	0.0%	0	0.0%	1
Gastrointestinal Disorders	**12**	**75.0%**	**2**	**12.5%**	**2**	**12.5%**	**16**
Constipation	0	0.0%	0	0.0%	1	100.0%	1
Dysphagia	11	91.7%	1	8.3%	0	0.0%	12
Gastroesophageal Reflux Disease	1	100.0%	0	0.0%	0	0.0%	1
Obstruction, Specify Location	0	0.0%	0	0.0%	1	100.0%	1
Other Gastrointestinal Disorder	0	0.0%	1	100.0%	0	0.0%	1

	Mild		Moderate		Severe		Total
	Events	%*	Events	%*	Events	%*	Events
General Disorders and Administrative Site Conditions	**1**	**100.0%**	**0**	**0.0%**	**0**	**0.0%**	**1**
Fever	1	100.0%	0	0.0%	0	0.0%	1
Immune System Disorders	**0**	**0.0%**	**1**	**100.0%**	**0**	**0.0%**	**1**
Foreign Body Reaction, Implant Material	0	0.0%	1	100.0%	0	0.0%	1
Infections and Infestations	**2**	**25.0%**	**5**	**62.5%**	**1**	**12.5%**	**8**
Appendicitis	0	0.0%	0	0.0%	1	100.0%	1
Sinusitis	1	50.0%	1	50.0%	0	0.0%	2
Herpes zoster	0	0.0%	1	100.0%	0	0.0%	1
Respiratory Tract Infection	1	50.0%	1	50.0%	0	0.0%	2
Urinary Tract Infection	0	0.0%	2	100.0%	0	0.0%	2
Metabolism and Nutrition Disorders	**1**	**100.0%**	**0**	**0.0%**	**0**	**0.0%**	**1**
Dehydration	1	100.0%	0	0.0%	0	0.0%	1
Musculoskeletal and Connective Tissue Disorders	**44**	**57.9%**	**27**	**35.5%**	**5**	**6.6%**	**76**
Arm Pain (not radicular)	5	100.0%	0	0.0%	0	0.0%	5
Cervical pain (no narcotic given)	8	40.0%	12	60.0%	0	0.0%	20
Cervical pain (narcotic given)	1	100.0%	0	0.0%	0	0.0%	1
Joint pain	3	50.0%	2	33.3%	1	16.7%	6
Joint stiffness	0	0.0%	1	100.0%	0	0.0%	1
Lumbar pain	4	36.4%	6	54.5%	1	9.1%	11
Neck stiffness	2	66.7%	1	33.3%	0	0.0%	3
Other Musculoskeletal Pain, Specify Location	2	66.7%	1	33.3%	0	0.0%	3
Spasms	3	75.0%	1	25.0%	0	0.0%	4
Lumbar Spinal Stenosis	0	0.0%	0	0.0%	2	100.0%	2
Osteoarthritis	1	100.0%	0	0.0%	0	0.0%	1
Shoulder Blade Pain	4	100.0%	0	0.0%	0	0.0%	4
Shoulder Pain	8	72.7%	2	18.2%	1	9.1%	11
Thoracic Pain	1	100.0%	0	0.0%	0	0.0%	1
Trapezius Pain	1	50.0%	1	50.0%	0	0.0%	2
Other Musculoskeletal and Connective Tissue Disorder	1	100.0%	0	0.0%	0	0.0%	1
Nervous System Disorders	**34**	**59.6%**	**19**	**33.3%**	**4**	**7.0%**	**57**
Compressive neuropathy	2	66.7%	1	33.3%	0	0.0%	3
Dizziness	3	100.0%	0	0.0%	0	0.0%	3
Headache	5	71.4%	2	28.6%	0	0.0%	7
numbness/tingling	1	100.0%	0	0.0%	0	0.0%	1
Paresthesia	1	100.0%	0	0.0%	0	0.0%	1
Radiculopathy (including radicular arm pain)	9	52.9%	6	35.3%	2	11.8%	17
Weakness	1	50.0%	1	50.0%	0	0.0%	2
Mononeuropathy	0	0.0%	0	0.0%	1	100.0%	1
Numbness/Tingling, Upper Extremity	10	55.6%	7	38.9%	1	5.6%	18
Peripheral Neuropathy	2	50.0%	2	50.0%	0	0.0%	4

	Mild		Moderate		Severe		Total
	Events	%*	Events	%*	Events	%*	Events
Psychiatric Disorders	**2**	**66.7%**	**1**	**33.3%**	**0**	**0.0%**	**3**
Anxiety Disorders	1	100.0%	0	0.0%	0	0.0%	1
Insomnia	1	50.0%	1	50.0%	0	0.0%	2
Renal and Urinary Disorders	**1**	**50.0%**	**1**	**50.0%**	**0**	**0.0%**	**2**
Renal Calculi	0	0.0%	1	100.0%	0	0.0%	1
Urinary Retention	1	100.0%	0	0.0%	0	0.0%	1
Reproductive System and Breast Disorders	**1**	**100.0%**	**0**	**0.0%**	**0**	**0.0%**	**1**
Other Reproductive System and Breast Disorder	1	100.0%	0	0.0%	0	0.0%	1
Respiratory, Thoracic and Mediastinal Disorders	**4**	**80.0%**	**0**	**0.0%**	**1**	**20.0%**	**5**
Dysphonia	2	100.0%	0	0.0%	0	0.0%	2
Nasal congestion	1	100.0%	0	0.0%	0	0.0%	1
Sleep apnea	1	100.0%	0	0.0%	0	0.0%	1
Airway obstruction	0	0.0%	0	0.0%	1	100.0%	1
Skin and Subcutaneous Tissue Disorders	**3**	**60.0%**	**2**	**40.0%**	**0**	**0.0%**	**5**
Cyst	0	0.0%	2	100.0%	0	0.0%	2
Hematoma	1	100.0%	0	0.0%	0	0.0%	1
Wound secretions / drainage	1	100.0%	0	0.0%	0	0.0%	1
Other Skin and Subcutaneous Tissue Disorder	1	100.0%	0	0.0%	0	0.0%	1
Vascular Disorders	**1**	**33.3%**	**1**	**33.3%**	**1**	**33.3%**	**3**
Angioedema	0	0.0%	1	100.0%	0	0.0%	1
Hypertension	1	100.0%	0	0.0%	0	0.0%	1
Transient Ischemic Attack	0	0.0%	0	0.0%	1	100.0%	1
Other Complications/Events	**5**	**62.5%**	**0**	**0.0%**	**3**	**37.5%**	**8**
Cancer	0	0.0%	0	0.0%	3	100.0%	3
Other Event, Describe	1	100.0%	0	0.0%	0	0.0%	1
Accident and injury	3	100.0%	0	0.0%	0	0.0%	3
Odynophagia	1	100.0%	0	0.0%	0	0.0%	1

*Percentage of total events for that specific AE code. Row percentages will sum to 100%.
Source: Tables Safety.sas; Analyzed: 19JUN2026

Device-Related Adverse Events

Table 66 presents all device-related AEs recorded in the AT Analysis Set classified as possibly, probably, or definitely related to the study device. Overall, the investigational group presented with 26 device-related AEs in 8.1% (17/210) of the 210 BAGUERA® C subjects, compared to 8 device-related AEs in 7.1% (7/98) of the 98 Mobi-C subjects.

No device-related AE had a rate of 5% or more. The majority of device-related AEs occurred between Day 180 and Day 365 for the investigational group (n=7 AEs), and between Day 30 and Day 90 for the control group (n=3 AEs). Among device-related AEs, there were 12 mild AEs, 8 moderate AEs, and 6 severe AEs reported in the BAGUERA® C group in the AT population (N=210). Among device-related AEs, there were 1 mild AEs, 5 moderate AEs, and 2 Severe AEs reported in the Mobi-C control group in the AT population (N=98).

Table 66 All Device-Related Adverse Events (AT Analysis Set, N=308)

	BAGUERA® C (N= 210)			Mobi-C (N= 98)			Dif		
	Events	Subjs	%*	Events	Subjs	%*	%	LB†	UB†
All	**26**	**17**	**8.1%**	**8**	**7**	**7.1%**	**1.0%**	**-5.3%**	**7.2%**
Device (non-system specific)	**1**	**1**	**0.5%**	**1**	**1**	**1.0%**	**-0.5%**		
Implant Loosening	1	1	0.5%	0	0	0.0%	0.5%		
Implant Migration	0	0	0.0%	1	1	1.0%	-1.0%		
Immune System Disorders	**0**	**0**	**0.0%**	**1**	**1**	**1.0%**	**-1.0%**		
Foreign Body Reaction, Implant Material	0	0	0.0%	1	1	1.0%	-1.0%		
Musculoskeletal and Connective Tissue Disorders	**8**	**6**	**2.9%**	**2**	**2**	**2.0%**	**0.8%**		
Arm Pain (not radicular)	1	1	0.5%	0	0	0.0%	0.5%		
Cervical pain (no narcotic given)	1	1	0.5%	2	2	2.0%	-1.6%		
Neck stiffness	2	2	1.0%	0	0	0.0%	1.0%		
Spasms	1	1	0.5%	0	0	0.0%	0.5%		
Cervical Foraminal Stenosis	1	1	0.5%	0	0	0.0%	0.5%		
Shoulder Blade Pain	1	1	0.5%	0	0	0.0%	0.5%		
Shoulder Pain	1	1	0.5%	0	0	0.0%	0.5%		
Nervous System Disorders	**17**	**14**	**6.7%**	**4**	**4**	**4.1%**	**2.6%**		
Paresthesia	1	1	0.5%	0	0	0.0%	0.5%		
Radiculopathy (including radicular arm pain)	7	7	3.3%	2	2	2.0%	1.3%		
Temporary or permanent nerve damage	1	1	0.5%	0	0	0.0%	0.5%		
Weakness	2	2	1.0%	0	0	0.0%	1.0%		
Numbness/Tingling, Upper Extremity	6	6	2.9%	1	1	1.0%	1.8%		
Peripheral Neuropathy	0	0	0.0%	1	1	1.0%	-1.0%		

*Percentage of subjects experiencing specific event.
† 95% Asymptotic CI reported when at least five subjects experienced the AE and at least five subjects did not experience the AE.
Source: Tables Safety.sas; Analyzed: 19JUN2026

Procedure-Related Adverse Events

Table 67 presents all procedure-related AEs recorded in the AT Analysis Set classified as possibly, probably or definitely related to the study procedure. Overall, the investigational group presented with 76 procedure-related AEs in 25.2% (53/210) of the 210 BAGUERA® C subjects, compared to 47 procedure-related AEs in 24.5% (24/98) of the 98 Mobi-C subjects.

The most common procedure-related AEs included: dysphagia (investigational – 10.5%, 22/210; control – 11.2%, 11/98).

The majority of all procedure-related occurred between Day 0 and Day 2 for the investigational group (29 AEs), and between Day 0 and Day 2 for the control group (17 AEs). Among procedure-related AEs, there were 52 mild AEs, 20 moderate AEs, and 4 Severe AEs reported in the BAGUERA® C group in the AT population (n=210). Among procedure related AEs, there were 31 mild AEs, 11 moderate AEs, and 5 Severe AEs reported in the Mobi-C control group in the AT population (N=98).

Table 67 All Procedure-Related Adverse Events (AT Analysis Set, N=308)

	BAGUERA® C (N= 210)			Mobi-C (N= 98)			Diff.		
	AEs	Subjs	%*	AEs	Subjs	%*	%	LB†	UB†
All	**76**	**53**	**25.2%**	**47**	**24**	**24.5%**	**0.7%**	**-9.6%**	**11.1%**
Blood and Lymphatic System Disorders	**0**	**0**	**0.0%**	**1**	**1**	**1.0%**	**-1.0%**		
Blood Clots (non-pulmonary)	0	0	0.0%	1	1	1.0%	-1.0%		
Device (non system specific)	**0**	**0**	**0.0%**	**1**	**1**	**1.0%**	**-1.0%**		
Implant Migration	0	0	0.0%	1	1	1.0%	-1.0%		
Ear and Labyrinth Disorders	**1**	**1**	**0.5%**	**0**	**0**	**0.0%**	**0.5%**		
Vertigo	1	1	0.5%	0	0	0.0%	0.5%		
Eye Disorders	**1**	**1**	**0.5%**	**0**	**0**	**0.0%**	**0.5%**		
Other Eye Disorders	1	1	0.5%	0	0	0.0%	0.5%		
Gastrointestinal Disorders	**25**	**24**	**11.4%**	**12**	**12**	**12.2%**	**-0.8%**	**-8.6%**	**7.0%**
Constipation	0	0	0.0%	1	1	1.0%	-1.0%		
Dysphagia	22	22	10.5%	11	11	11.2%	-0.7%	-8.2%	6.7%
Gastroesophageal Reflux Disease	1	1	0.5%	0	0	0.0%	0.5%		
Nausea	1	1	0.5%	0	0	0.0%	0.5%		
Other Gastrointestinal Disorder	1	1	0.5%	0	0	0.0%	0.5%		
General Disorders and Administrative Site Conditions	**1**	**1**	**0.5%**	**1**	**1**	**1.0%**	**-0.5%**		
Fever	0	0	0.0%	1	1	1.0%	-1.0%		
Incision Site Tenderness	1	1	0.5%	0	0	0.0%	0.5%		
Immune System Disorders	**1**	**1**	**0.5%**	**0**	**0**	**0.0%**	**0.5%**		
Allergic Reaction	1	1	0.5%	0	0	0.0%	0.5%		
Infections and Infestations	**3**	**2**	**1.0%**	**0**	**0**	**0.0%**	**1.0%**		
Infection, Not at Surgical Site	1	1	0.5%	0	0	0.0%	0.5%		
Urinary Tract Infection	1	1	0.5%	0	0	0.0%	0.5%		
Oropharyngeal Infection	1	1	0.5%	0	0	0.0%	0.5%		

	BAGUERA® C (N= 210)			Mobi-C (N= 98)			Diff.		
	AEs	Subjs	%*	AEs	Subjs	%*	%	LB†	UB†
Metabolism and Nutrition Disorders	**0**	**0**	**0.0%**	**1**	**1**	**1.0%**	**-1.0%**		
Dehydration	0	0	0.0%	1	1	1.0%	-1.0%		
Musculoskeletal and Connective Tissue Disorders	**15**	**13**	**6.2%**	**10**	**7**	**7.1%**	**-1.0%**	**-7.0%**	**5.1%**
Arm Pain (not radicular)	1	1	0.5%	2	1	1.0%	-0.5%		
Cervical pain (no narcotic given)	5	5	2.4%	4	4	4.1%	-1.7%		
Cervical pain (narcotic given)	1	1	0.5%	0	0	0.0%	0.5%		
Neck stiffness	2	2	1.0%	0	0	0.0%	1.0%		
Spasms	1	1	0.5%	2	2	2.0%	-1.6%		
Cervical Foraminal Stenosis	1	1	0.5%	0	0	0.0%	0.5%		
Shoulder Blade Pain	3	3	1.4%	1	1	1.0%	0.4%		
Shoulder Pain	1	1	0.5%	0	0	0.0%	0.5%		
Trapezius Pain	0	0	0.0%	1	1	1.0%	-1.0%		
Nervous System Disorders	**17**	**14**	**6.7%**	**13**	**11**	**11.2%**	**-4.6%**	**-11.7%**	**2.5%**
Numbness/tingling	1	1	0.5%	1	1	1.0%	-0.5%		
Paresthesia	1	1	0.5%	0	0	0.0%	0.5%		
Radiculopathy (including radicular arm pain)	7	7	3.3%	3	3	3.1%	0.3%		
Temporary or permanent nerve damage	1	1	0.5%	0	0	0.0%	0.5%		
Weakness	2	2	1.0%	0	0	0.0%	1.0%		
Mononeuropathy	0	0	0.0%	1	1	1.0%	-1.0%		
Numbness/Tingling, Upper Extremity	5	5	2.4%	7	5	5.1%	-2.7%	-7.5%	2.1%
Peripheral Neuropathy	0	0	0.0%	1	1	1.0%	-1.0%		
Respiratory, Thoracic and Mediastinal Disorders	**9**	**9**	**4.3%**	**3**	**3**	**3.1%**	**1.2%**		
Cough	2	2	1.0%	0	0	0.0%	1.0%		
Dysphonia	3	3	1.4%	2	2	2.0%	-0.6%		
Dyspnea	1	1	0.5%	0	0	0.0%	0.5%		
Hoarseness	3	3	1.4%	0	0	0.0%	1.4%		
Airway obstruction	0	0	0.0%	1	1	1.0%	-1.0%		
Skin and Subcutaneous Tissue Disorders	**3**	**3**	**1.4%**	**2**	**2**	**2.0%**	**-0.6%**		
Hematoma	0	0	0.0%	1	1	1.0%	-1.0%		
Wound complications (eg., dehiscence, bruising) and soft tissue damage	3	3	1.4%	0	0	0.0%	1.4%		
Wound secretions / drainage	0	0	0.0%	1	1	1.0%	-1.0%		
Vascular Disorders	**0**	**0**	**0.0%**	**1**	**1**	**1.0%**	**-1.0%**		
Angioedema	0	0	0.0%	1	1	1.0%	-1.0%		
Other Complications/Events	**0**	**0**	**0.0%**	**2**	**2**	**2.0%**	**-2.0%**		
Other Event, Describe	0	0	0.0%	1	1	1.0%	-1.0%		
Odynophagia	0	0	0.0%	1	1	1.0%	-1.0%		

*Percentage of subjects experiencing specific event.
† 95% Asymptotic CI reported when at least five subjects experienced the AE and at least five subjects did not experience th e AE.
Source: Tables Safety.sas; Analyzed: 19JUN2026

Serious Adverse Events

Table 68 below presents a summary of all SAEs for all investigational BAGUERA® C subjects and Mobi-C control subjects in the AT analysis population (N=308). There were 79 SAEs in 25.7% (54/210) of the BAGUERA® C subjects and 30 SAEs in 24.5% (24/98) of the Mobi-C control group subjects as determined by the CEC. The most common SAE body system sub-category was radiculopathy in both the investigational group (2.9%; 6/210) and control group (6.1%; 6/98).

Table 68 Serious Adverse Events by AE Code – At Analysis Set (N=308)

	BAGUERA® C (N= 210)			Mobi-C (N= 98)			Dif		
	AEs	Subjs	%*	AEs	Subjs	%*	%	LB†	UB†
All	**79**	**54**	**25.7%**	**30**	**24**	**24.5%**	**1.2%**	**-9.1%**	**11.6%**
Cardiac Disorders	**1**	**1**	**0.5%**	**1**	**1**	**1.0%**	**-0.5%**		
Atrial Fibrillation	1	1	0.5%	0	0	0.0%	0.5%		
Mitral Valve Disease	0	0	0.0%	1	1	1.0%	-1.0%		
Device (non system specific)	**1**	**1**	**0.5%**	**1**	**1**	**1.0%**	**-0.5%**		
Implant Loosening	1	1	0.5%	0	0	0.0%	0.5%		
Implant Migration	0	0	0.0%	1	1	1.0%	-1.0%		
Endocrine Disorders	**1**	**1**	**0.5%**	**0**	**0**	**0.0%**	**0.5%**		
Hypothyroidism	1	1	0.5%	0	0	0.0%	0.5%		
Eye Disorders	**3**	**3**	**1.4%**	**0**	**0**	**0.0%**	**1.4%**		
Blurred Vision	1	1	0.5%	0	0	0.0%	0.5%		
Retinal Detachment	1	1	0.5%	0	0	0.0%	0.5%		
Other Eye Disorders	1	1	0.5%	0	0	0.0%	0.5%		
Gastrointestinal Disorders	**4**	**4**	**1.9%**	**1**	**1**	**1.0%**	**0.9%**		
Dysphagia	1	1	0.5%	0	0	0.0%	0.5%		
Obstruction, Specify Location	1	1	0.5%	1	1	1.0%	-0.5%		
Other Gastrointestinal Disorder	2	2	1.0%	0	0	0.0%	1.0%		
General Disorders and Administrative Site Conditions	**1**	**1**	**0.5%**	**0**	**0**	**0.0%**	**0.5%**		
Hernia	1	1	0.5%	0	0	0.0%	0.5%		
Hepatobiliary Disorders	**1**	**1**	**0.5%**	**0**	**0**	**0.0%**	**0.5%**		
Gallbladder Pain	1	1	0.5%	0	0	0.0%	0.5%		
Immune System Disorders	**1**	**1**	**0.5%**	**1**	**1**	**1.0%**	**-0.5%**		
Foreign Body Reaction, Implant Material	0	0	0.0%	1	1	1.0%	-1.0%		
Inflammatory Condition	1	1	0.5%	0	0	0.0%	0.5%		
Infections and Infestations	**3**	**3**	**1.4%**	**1**	**1**	**1.0%**	**0.4%**		
Appendicitis	1	1	0.5%	1	1	1.0%	-0.5%		
COVID-19 Infection	1	1	0.5%	0	0	0.0%	0.5%		
Herpes zoster	1	1	0.5%	0	0	0.0%	0.5%		
Musculoskeletal and Connective Tissue Disorders	**35**	**28**	**13.3%**	**9**	**8**	**8.2%**	**5.2%**	**-1.9%**	**12.3%**
Arm Pain (not radicular)	1	1	0.5%	0	0	0.0%	0.5%		
Cervical pain (no narcotic given)	2	2	1.0%	0	0	0.0%	1.0%		
Joint pain	7	6	2.9%	4	4	4.1%	-1.2%		
Lumbar pain	2	2	1.0%	2	2	2.0%	-1.1%		
Neck stiffness	1	1	0.5%	0	0	0.0%	0.5%		

	BAGUERA® C (N= 210)			Mobi-C (N= 98)			Dif		
	AEs	Subjs	%*	AEs	Subjs	%*	%	LB†	UB†
Spasms	2	2	1.0%	0	0	0.0%	1.0%		
Cervical Foraminal Stenosis	1	1	0.5%	0	0	0.0%	0.5%		
Lumbar Spinal Stenosis	3	3	1.4%	2	2	2.0%	-0.6%		
Muscle Rupture	1	1	0.5%	0	0	0.0%	0.5%		
Osteoarthritis	3	3	1.4%	0	0	0.0%	1.4%		
Shoulder Pain	7	7	3.3%	1	1	1.0%	2.3%		
Thoracic Pain	1	1	0.5%	0	0	0.0%	0.5%		
Trigger Finger	1	1	0.5%	0	0	0.0%	0.5%		
Fracture, Any Bone	3	3	1.4%	0	0	0.0%	1.4%		
Nervous System Disorders	**16**	**11**	**5.2%**	**8**	**8**	**8.2%**	**-2.9%**	**-9.1%**	**3.3%**
Compressive neuropathy	4	3	1.4%	0	0	0.0%	1.4%		
Coordination abnormalities	3	2	1.0%	0	0	0.0%	1.0%		
Radiculopathy (including radicular arm pain)	7	6	2.9%	6	6	6.1%	-3.3%	-8.5%	2.0%
Weakness	1	1	0.5%	0	0	0.0%	0.5%		
Mononeuropathy	0	0	0.0%	1	1	1.0%	-1.0%		
Numbness/Tingling, Upper Extremity	1	1	0.5%	1	1	1.0%	-0.5%		
Renal and Urinary Disorders	**4**	**4**	**1.9%**	**0**	**0**	**0.0%**	**1.9%**		
Renal Calculi	4	4	1.9%	0	0	0.0%	1.9%		
Respiratory, Thoracic and Mediastinal Disorders	**2**	**2**	**1.0%**	**2**	**2**	**2.0%**	**-1.1%**		
Nasal congestion	0	0	0.0%	1	1	1.0%	-1.0%		
Sore throat	1	1	0.5%	0	0	0.0%	0.5%		
Pulmonary embolism	1	1	0.5%	0	0	0.0%	0.5%		
Airway obstruction	0	0	0.0%	1	1	1.0%	-1.0%		
Skin and Subcutaneous Tissue Disorders	**1**	**1**	**0.5%**	**3**	**3**	**3.1%**	**-2.6%**		
Cyst	1	1	0.5%	2	2	2.0%	-1.6%		
Other Skin and Subcutaneous Tissue Disorder	0	0	0.0%	1	1	1.0%	-1.0%		
Other Complications/Events	**5**	**5**	**2.4%**	**3**	**3**	**3.1%**	**-0.7%**		
Cancer	4	4	1.9%	3	3	3.1%	-1.2%		
Other Event, Describe	1	1	0.5%	0	0	0.0%	0.5%		

*Percentage of subjects experiencing specific event.
† 95% Asymptotic CI reported when at least five subjects experienced the AE and at least five subjects did not experience th e AE.
Source: Tables Safety.sas; Analyzed: 19JUN2026

Serious Adverse Events by Time course

Table 69 presents the SAEs through Month 24 for both treatment groups. The majority of SAEs occurred between Day 365 and Day 730 (35) for the investigational group, and between Day 180 and Day 365 (10) for the control group. While not shown, the majority of all device-related SAEs occurred between Day 365 and Day 730 (4) for the investigational group, and between Day 180 and Day 365 (1) for the control group.

Table 69 Serious Adverse Events (Time course) – AT Analysis Set, N=308

	Days Post-Op															
	<0		0-2		2-30		30-90		90-180		180-365		365-730		Total	
	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C
All	**0**	**0**	**3**	**2**	**4**	**1**	**9**	**7**	**10**	**5**	**18**	**10**	**35**	**5**	**79**	**30**
Cardiac Disorders	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**0**	**0**	**0**	**1**	**0**	**1**	**1**
Atrial Fibrillation	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0
Mitral Valve Disease	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1
Endocrine Disorders	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**0**	**0**	**1**	**0**
Hypothyroidism	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0
Eye Disorders	**0**	**0**	**1**	**0**	**0**	**0**	**1**	**0**	**1**	**0**	**0**	**0**	**0**	**0**	**3**	**0**
Blurred Vision	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	0
Retinal Detachment	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1	0
Other Eye Disorders	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1	0
Gastrointestinal Disorders	**0**	**0**	**1**	**0**	**0**	**0**	**1**	**0**	**1**	**0**	**0**	**0**	**1**	**1**	**4**	**1**
Dysphagia	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1	0
Obstruction, Specify Location	0	0	0	0	0	0	0	0	0	0	0	0	1	1	1	1
Other Gastrointestinal Disorder	0	0	0	0	0	0	1	0	1	0	0	0	0	0	2	0
General Disorders and Administrative Site Conditions	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**1**	**0**
Hernia	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0
Hepatobiliary Disorders	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**0**	**0**	**1**	**0**
Gallbladder Pain	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0
Immune System Disorders	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**0**	**1**	**0**	**1**	**1**
Foreign Body Reaction, Implant Material	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1
Inflammatory Condition	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0
Infections and Infestations	**0**	**0**	**1**	**0**	**0**	**0**	**0**	**0**	**1**	**1**	**1**	**0**	**0**	**0**	**3**	**1**
Appendicitis	0	0	0	0	0	0	0	0	1	1	0	0	0	0	1	1
COVID-19 Infection	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0
Herpes zoster	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1	0
Musculoskeletal and Connective Tissue Disorders	**0**	**0**	**0**	**0**	**3**	**0**	**4**	**2**	**5**	**3**	**10**	**4**	**13**	**0**	**35**	**9**
Arm Pain (not radicular)	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1	0
Cervical pain (no narcotic given)	0	0	0	0	0	0	1	0	1	0	0	0	0	0	2	0
Joint pain	0	0	0	0	0	0	2	1	0	1	1	2	4	0	7	4
Lumbar pain	0	0	0	0	1	0	0	0	0	2	1	0	0	0	2	2
Neck stiffness	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	0
Spasms	0	0	0	0	0	0	0	0	0	0	1	0	1	0	2	0

	Days Post-Op															
	<0		0-2		2-30		30-90		90-180		180-365		365-730		Total	
	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C
Cervical Foraminal Stenosis	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1	0
Lumbar Spinal Stenosis	0	0	0	0	0	0	0	1	0	0	2	1	1	0	3	2
Muscle Rupture	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0
Osteoarthritis	0	0	0	0	0	0	0	0	1	0	0	0	2	0	3	0
Shoulder Pain	0	0	0	0	0	0	0	0	1	0	2	1	4	0	7	1
Thoracic Pain	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1	0
Trigger Finger	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0
Fracture, Any Bone	0	0	0	0	0	0	0	0	1	0	2	0	0	0	3	0
Nervous System Disorders	**0**	**0**	**0**	**0**	**1**	**1**	**2**	**2**	**2**	**0**	**2**	**3**	**9**	**2**	**16**	**8**
Compressive neuropathy	0	0	0	0	0	0	0	0	0	0	1	0	3	0	4	0
Coordination abnormalities	0	0	0	0	0	0	2	0	0	0	0	0	1	0	3	0
Radiculopathy (including radicular arm pain)	0	0	0	0	0	0	0	1	1	0	1	3	5	2	7	6
Weakness	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1	0
Mononeuropathy	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1
Numbness/Tingling, Upper Extremity	0	0	0	0	0	0	0	1	1	0	0	0	0	0	1	1
Renal and Urinary Disorders	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**2**	**0**	**2**	**0**	**4**	**0**
Renal Calculi	0	0	0	0	0	0	0	0	0	0	2	0	2	0	4	0
Respiratory, Thoracic and Mediastinal Disorders	**0**	**0**	**0**	**1**	**0**	**0**	**0**	**1**	**0**	**0**	**0**	**0**	**2**	**0**	**2**	**2**
Nasal congestion	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1
Sore throat	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0
Pulmonary embolism	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0
Airway obstruction	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1
Skin and Subcutaneous Tissue Disorders	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**1**	**0**	**0**	**0**	**2**	**0**	**0**	**1**	**3**
Cyst	0	0	0	0	0	0	1	1	0	0	0	1	0	0	1	2
Other Skin and Subcutaneous Tissue Disorder	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1
Device (non system specific)	**0**	**0**	**0**	**1**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**1**	**1**
Implant Loosening	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0
Implant Migration	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1
Other Complications/Events	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**1**	**4**	**2**	**5**	**3**
Cancer	0	0	0	0	0	0	0	0	0	0	1	1	3	2	4	3
Other Event, Describe	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0

Source: Tables Safety.sas; Analyzed: 19JUN2026

Secondary Surgical Interventions

Some AEs resulted in Secondary Surgical Interventions (SSIs) that were prospectively classified as revisions, removals, reoperations or supplemental fixations, qualified as study failures in accordance with FDA's Guidance Document, Clinical Data Presentations for Orthopedic Device Applications (2004) and were reviewed and adjudicated by the CEC.

Based on the results presented in Table 70, a total of six (6) SSIs occurred in the investigational group (two subjects experienced two SSIs each), and four (4) SSIs occurred in the control group. The time course of these events demonstrates that the majority of SSIs occurred between 6 and 12 months in the investigational group, white the majority of SSIs occurred between Day 1 and Week 6 in the control group; however, meaningful conclusions cannot be made with respect to timing due to the low number of SSI events in both groups.

Table 70 SSI Time course by Treatment Type – AT Analysis Set, N = 308

Treatment Group	Event Time-Course (months)						Total Subjects
	SSI Type	< 1.5	1.5-3	3-6	6-12	12-24	
BAGUERA C	Removal	-	1	-	1	1	3
	Revision	-	-	-	-	-	-
	Reoperation	1	-	1	-	-	2
	Supplemental Fixation	-	-	-	1	-	1
Total Events (subjects)		**1**	**1**	**1**	**2**	**1**	**6**
Mobi-C (Control)	Removal	1	1	1	-	-	3
	Revision	-	-	-	-	-	-
	Reoperation	1	-	-	-	-	1
	Supplemental Fixation	-	-	-	-	-	-
Total Events (subjects)		**2**	**1**	**1**	**-**	**-**	**4**

The procedure and reason for SSI are detailed below in Table 71. Of the six (6) SSIs observed in the BAGUERA® C investigational group, three (3) resulted in device removal. Of the four (4) SSIs reported in the Mobi-C control cohort, three (3) resulted in device removal.

Table 71 Surgical Intervention Procedure and Indication for Procedure.

Group	Procedure	Index Level	Procedure	Indication for Procedure
BAGUERA® C	Removal	C5-C7	Explant of BAGUERA® C devices and ACDF at C5-C7	Worsening radicular symptoms and upper extremity pain. Residual stenosis at C5-C6
BAGUERA® C [1]	Reoperation	C5-C7	Hemilaminectomy with partial medial facetectomy at left C5-C7	Foraminal stenosis at left C5-C7
BAGUERA® C [1]	Removal	C5-C7	Explant of BAGUERA® C devices and ACDF at C5-C7	Persistent cervical radiculopathy
BAGUERA® C [2]	Supplemental Fixation	C5-C7	Posterior fusion at C5-C7	Bilateral Upper Extremity Pain
BAGUERA® C [2]	Removal	C5-C7	Explant of the BAGUERA® C devices, and ACDF at C5-C7	Loosening of left C5 and bilateral C7 posterior cervical screws
BAGUERA® C	Reoperation	C4-C6	Hemilaminotomies and foraminotomies at C4-C6	C5 palsy causing upper extremity weakness
Mobi-C	Reoperation	C4-C6	Foraminotomy at C4-C5	Postoperative Right Deltoid Palsy
Mobi-C	Removal	C5-C7	Explant of the Mobi-C device and replacement with new Mobi-C device	Implant Loosening
Mobi-C	Removal	C5-C7	Explant of the Mobi-C devices and ACDF at C5-C7	Allergic reaction to Mobi-C device
Mobi-C	Removal	C5-C7	Explant of the Mobi-C devices and ACDF at C5-C7	Radiculopathy

[1]: SSIs experienced by the same study patient
[2]: SSIs experienced by the same study patient

Neurological Status

The following tables specify the number and percentage of subjects who improved, maintained, or deteriorated in neurological status at each protocol-required follow-up. At 24 months, 95.2% of BAGUERA® C subjects and 94.0% of Mobi-C subjects experienced maintenance or improvement in sensory status relative to baseline (Table 72).

Table 72 Change in Neurological Sensory Status at Month 12 and Month 24 (Primary Analysis Population)

	Month 12						Month 24					
	I			C			I			C		
Sensory Status	n	N	%	n	N	%	n	N	%	n	N	%
Deteriorated	8	203	3.9	4	89	4.5	9	189	4.8	5	84	6.0
Maintained	82	203	40.4	34	89	38.2	79	189	41.8	32	84	38.1
Improved	113	203	55.7	51	89	57.3	101	189	53.4	47	84	56.0
Source: Tables Neuro Status.sas; Analyzed: 13JUL2026												

At 24 months 97.8% of BAGUERA C and 98.8% on Mobi-C Subjects maintained or improved in reflex status relative to baseline (Table 73).

Table 73 Change in Neurological Reflex Status at Month 12 and Month 24 (Primary Analysis Population)

	Month 12						Month 24					
	I			C			I			C		
Reflex Status	**n**	**N**	**%**	**n**	**N**	**%**	**n**	**N**	**%**	**n**	**N**	**%**
Deteriorated	9	203	4.4	2	89	2.2	5	189	2.6	1	84	1.2
Maintained	141	203	69.5	62	89	69.7	132	189	69.8	60	84	71.4
Improved	53	203	26.1	25	89	28.1	52	189	27.5	23	84	27.4
Source: Tables Neuro Status.sas; Analyzed: 13JUL2026												

At 24 months, 98.9% of BAGUERA C and 98.8% of Mobi-C subjects maintained or improved in motor status relative to baseline (Table 74).

Table 74 Change in Neurological Motor Status at Month 12 and Month 24 (Primary Analysis Population)

	Month 12						Month 24					
	I			C			I			C		
Motor Status	**n**	**N**	**%**	**n**	**N**	**%**	**n**	**N**	**%**	**n**	**N**	**%**
Deteriorated	5	203	2.5%	1	89	1.1%	2	189	1.1%	1	84	1.2%
Maintained	181	203	89.2%	83	89	93.3%	170	189	89.9%	78	84	92.9%
Improved	17	203	8.4%	5	89	5.6%	17	189	9.0%	5	84	6.0%
Source: Tables Neuro Status.sas; Analyzed: 13JUL2026												

Neurological success was defined as maintenance or improvement in neurologic status at Month 24. The CEC reviewed investigator assigned neurologic status at Month 24 as compared to baseline for all subjects demonstrated a negative change in neurologic status to determine if the change was clinical relevant to the index level. At Month 24, one (1) BAGUERA® C subject were considered a neurological failure (0.5% - 1/189) and no (0) Mobi-C control subject was considered a neurological failure (0% - 0/84).

b) Effectiveness Results

The analysis of effectiveness was based on 307 subjects (209 investigational; 98 control) evaluable for primary CCS at Month 24. Key effectiveness outcomes are presented in Table 75.

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

Primary Composite Clinical Success Analysis

A subject was considered a study success at the Month 24 if he/she met all of the following criteria:

1. Improvement in pain and function, as measured through the Neck Disability Index (NDI), of at least 15 percentage points (out of 100%) from pre-operative;
2. Maintenance or improvement in neurological status at 24 months compared to baseline (as determined by the CEC);
3. No secondary surgical intervention defined as revision, removal, reoperation, or supplemental fixation at the index level;
4. No serious adverse event(s) confirmed as device or procedure related (as determined by the CEC).

Overall success was determined based on the PP Analysis Set at Month 24. The primary overall success outcomes are presented in Table 75.

Table 75 Overall success (PP Analysis, N=307)

	BAGUERA® C			Mobi-C			Group Difference				
	N	n	%	N	n	%	Δ[1]	LB[2]	UB[2]		
[1] No Secondary Surgical Intervention	209	205	98.1%	98	94	95.9%	2.2%	-1.8%	8.5%		
[2] No Serious Adverse Events (CEC)	209	206	98.6%	98	95	96.9%	1.6%	-1.9%	7.4%		
[3] NDI 15-Point Responder	189	179	94.7%	82	81	98.8%	-4.1%	-8.7%	2.1%		
[4] No Neurological Deterioration (CEC)	187	186	99.5%	83	83	>99.9	-0.5%	-3.1%	4.2%		
Composite Clinical Success							**Δ[3]**	**LB[4]**	**UB[4]**	**PostProb NI[5]**	**PredProb NI[6]**
[5] CCS with Bayesian Imputation	209	-	90.0%	98	-	93.0%	-3.0%	-9.1%	3.8%	>99.9%	>99.9%
Sensitivity Analysis 1							**Δ[3]**	**LB[4]**	**UB[4]**	**PostProb NI[5]**	
[6] CCS Complete Case Analysis	192	174	90.6%	85	80	94.1%	-2.9%	-9.3%	4.3%	99.9%	
Sensitivity Analysis 2							**Δ**	**LB**	**UB**	**1-Sided LB[7]**	
[7] CCS Frequentist Imputation Analysis	209	-	90.4%	98	-	92.1%	-1.7%	-9.2%	5.7%	-8.0%	

[1]Difference in binomial proportions.
[2]Exact 95% CI for difference of proportions.
[3]Difference in mean of beta posteriors.
[4]Quantile based 95% posterior credible interval.
[5]Posterior Probability of Non-Inferiority
[6]Predictive Probability of Non-Inferiority (NI) (δ = -12.5%).
[7]1-Sided 95% Confidence Interval Lower Bound
All Bayesian distributions calculated from Beta(1,1) prior.
Results derived from 50000 separate sets of imputations with 10000 samples drawn for calculation of posterior probabilities.
Posterior credible intervals estimated using 50000 samples.
Source: Tables Bayesian Interim.R; Analyzed: June 29, 2026

The imputed success rate for the investigational group was 90.0% as compared to an imputed success rate of 93.0% for the control group (difference -3.0% and 95% Bayesian Credible Interval for the difference [-9.1%, 3.8%]. Posterior probability is shown to demonstrate that non-inferiority has been achieved. In this study, the posterior probability of greater than 99.9% indicates there is greater than 99.9% 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 95% to declare success, which was achieved in this analysis.

A secondary supporting sensitivity analysis of the primary endpoint was performed with no imputation on the PP analysis set. The results were similar, with a success rate of 90.6% (174/192) as compared to a success rate of 94.1% (80/85) for the control group. Non-inferiority was also demonstrated in this secondary analysis.

Composite Clinical Success Subcomponents

In looking at the individual subcomponents of the CCS in Table 75, the results are similar between both treatment groups. Row [1] identifies that 98.1% (205/209) of the investigational subjects and 95.9% (94/98) of the control subjects did not experience an SSI. Row [2] identifies that 98.6% (206/209) of the investigational subjects and 96.9% (95/98) of the control subjects did not experience serious AE definitely related to the device or procedure. Row [3] indicates that 94.7% (179/189) of the investigational subjects and 98.8% (81/82) 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 99.5% (186/187) of the investigational subjects and >99.9% (83/83) of the control subjects did not experience neurological deterioration.

Secondary Effectiveness Analysis

In addition to the CCS subcomponents, a number of secondary endpoints were evaluated in the mITT analysis set (n=309), including: neck pain, shoulder/arm pain, and subject quality of life as discussed in Section X.B.1.d.

Neck Disability Index (NDI)

Table 76 shows the mean NDI score for the mITT Analysis Set over time through Month 24. In the investigational group, the mean NDI score decreased from 58.0 at screening to 12.2 at Month 24. In the control group, the mean NDI score decreased from 60.5 at screening to 12.4 at Month 24.

Table 76 NDI score values over time (mITT Analysis Set, N=309)

	BAGUERA® C						Control						Group Difference	
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	Diff.	p*
Screening	210	58.0	15.2	58.0	30.0	94.0	98	60.5	15.9	60.0	30.0	100.0	-2.5	0.124
Week 06	208	21.8	16.3	18.0	0.0	78.0	94	23.0	17.3	19.0	0.0	80.0	-1.1	0.352
Month 03	204	15.2	14.9	10.0	0.0	66.0	94	17.2	14.8	14.0	0.0	60.0	-2.0	0.116
Month 06	201	13.1	15.8	8.0	0.0	76.0	92	15.0	14.5	13.0	0.0	62.0	-1.9	0.068
Month 12	201	12.6	14.8	8.0	0.0	70.0	89	14.7	14.5	12.0	0.0	66.0	-2.1	0.067
Month 24	189	12.2	14.2	8.0	0.0	66.0	82	12.4	12.9	8.0	0.0	50.0	-0.2	0.332

*Two-sided 95% Wilcoxon Rank Sum test.
Source: Tables Clinical Follow-up.sas; Analyzed: 08JUL2026

Table 77 presents the number and percentage of subjects showing an improvement in NDI score greater than 15 percentage points as compared to all subjects in the study at each follow up time point for both the investigational and control groups. At Month 24, 94.7% (179/189) of investigational subjects achieved greater than a 15-percentage point improvement in NDI score as compared to baseline, while 98.8% (81/82) of control subjects achieved greater than a 15-percentage point improvement in NDI score as compared to baseline.

Table 77 NDI 15-Percentage Point Responder (mITT Analysis Set, N=309)

	BAGUERA® C			Control			Group Difference*			
	N	n	%	N	n	%	Δ	LB	UB	p
Week 06	208	182	87.5%	94	84	89.4%	-1.9%	-9.5%	5.8%	0.644
Month 03	204	187	91.7%	94	86	91.5%	0.2%	-6.6%	7.0%	0.959
Month 06	201	187	93.0%	92	87	94.6%	-1.5%	-7.3%	4.3%	0.622
Month 12	201	189	94.0%	89	84	94.4%	-0.4%	-6.2%	5.4%	0.906
Month 24	189	179	94.7%	82	81	98.8%	-4.1%	-8.0%	-0.1%	0.119

*Device group differences, Nominal 95% CI, and two-sided asymptotic p-value.
Source: Tables Clinical Follow-up.sas; Analyzed: 08JUL2026

VAS Neck Pain

Table 78 reports the mean VAS – Neck Pain score for the mITT Analysis Set over time through Month 24. In the investigational group, the mean VAS – Neck Pain score decreased from 75.0 at screening to 13.1 at Month 24. In the control group, the mean VAS – Neck Pain score decreased from 77.4 at screening to 14.4 at Month 24.

Table 78 VAS Pain (Neck) values over time (mITT Analysis Set, N=309)

	BAGUERA® C						Control						Group Difference	
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	Diff.	p*
Screening	210	75.0	18.0	77.5	1.0	100.0	98	77.4	18.3	81.0	13.0	100.0	-2.4	0.093
Week 06	208	19.8	23.0	10.0	0.0	97.0	93	23.5	24.8	13.0	0.0	93.0	-3.7	0.048
Month 03	204	14.6	19.0	6.5	0.0	90.0	94	19.6	22.8	11.0	0.0	100.0	-5.0	0.037
Month 06	201	14.9	22.4	4.0	0.0	100.0	93	16.8	20.3	8.0	0.0	93.0	-1.9	0.048
Month 12	201	15.2	22.0	4.0	0.0	94.0	89	14.7	21.6	5.0	0.0	93.0	0.6	0.485
Month 24	189	13.1	20.9	3.0	0.0	84.0	82	14.4	21.4	3.5	0.0	99.0	-1.3	0.276

*Two-sided 95% Wilcoxon Rank Sum test.
Source: Tables Clinical Follow-up.sas; Analyzed: 08JUL2026

Table 79 presents the number and percentage of subjects showing an improvement in VAS – Neck Pain score greater than 20 points as compared to all subjects in the study at each follow up time point for both the investigational and control groups. At Month 24, 94.6% (176/186) of investigational subjects achieved greater than a 20-point improvement in VAS – Neck Pain score as compared to baseline, while 92.6% (75/81) of control subjects achieved greater than a 20 point improvement in VAS – Neck pain score as compared to baseline.

Table 79 VAS Pain (Neck) Responder (mITT Analysis Set, N=309)

	BAGUERA® C			Control			Group Difference*			
	N	n	%	N	n	%	Δ	LB	UB	p
Week 06	205	181	88.3%	92	77	83.7%	4.6%	-4.1%	13.3%	0.278
Month 03	201	189	94.0%	93	85	91.4%	2.6%	-3.9%	9.2%	0.405
Month 06	198	183	92.4%	92	87	94.6%	-2.1%	-8.1%	3.8%	0.503
Month 12	198	184	92.9%	88	81	92.0%	0.9%	-5.8%	7.6%	0.791
Month 24	186	176	94.6%	81	75	92.6%	2.0%	-4.5%	8.6%	0.520

*Device group differences, Nominal 95% CI, and two-sided asymptotic p-value.
Restricted to subjects with baseline VAS Neck of 20 points or greater.
Source: Tables Clinical Follow-up.sas; Analyzed: 08JUL2026

VAS Right Arm/Shoulder Pain

Table 80 describes the mean VAS – Right Shoulder/Arm Pain score for the mITT Analysis Set over time through Month 24. In the investigational group, the mean VAS – Right Shoulder/Arm Pain score decreased from 44.4 at screening to 8.8 at Month 24. In the control group, the mean VAS– Right Shoulder/Arm Pain score decreased from 52.8 at screening to 9.1 at Month 24.

Table 80 VAS Pain (Right Shoulder/Arm) values over time (mITT Analysis Set, N=309)

	BAGUERA® C						Control						Group Difference	
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	Dif	p*
Screening	210	44.2	37.0	46.5	0.0	100.0	98	52.8	35.4	59.5	0.0	100.0	-8.5	0.023
Week 06	207	13.8	23.0	1.0	0.0	97.0	93	12.7	21.9	2.0	0.0	96.0	1.1	0.489
Month 03	204	9.9	19.8	0.5	0.0	91.0	94	11.4	20.8	1.5	0.0	100.0	-1.5	0.126
Month 06	200	9.6	19.6	0.0	0.0	88.0	93	9.9	17.0	1.0	0.0	80.0	-0.3	0.111
Month 12	201	9.5	18.6	1.0	0.0	93.0	89	9.1	19.5	0.0	0.0	93.0	0.4	0.142
Month 24	189	8.8	18.2	0.0	0.0	81.0	82	9.1	19.9	0.0	0.0	87.0	-0.4	0.308

*Two-sided 95% Wilcoxon Rank Sum test.
Source: Tables Clinical Follow-up.sas; Analyzed: 08JUL2026

Table 81 identifies the number and percentage of subjects showing an improvement in VAS – Right Shoulder/Arm Pain score greater than 20 points as compared to all subjects in the study at each follow up time point for both the investigational and control groups. At Month 24, 94.0% (109/116) of investigational subjects achieved greater than a 20-point improvement in VAS – Right Shoulder/Arm Pain score as compared to baseline, while 88.1% (52/59) of control subjects achieved greater than a 20-point improvement in VAS – Right Shoulder/Arm Pain score as compared to baseline.

Table 81 VAS Right Shoulder/Arm Pain 20-Point Responder (mITT Analysis Set, N=309)

	BAGUERA® C			Control			Group Difference*			
	N	n	%	N	n	%	Δ	LB	UB	p
Week 06	127	102	80.3%	67	57	85.1%	-4.8%	-15.7%	6.2%	0.412
Month 03	125	108	86.4%	69	59	85.5%	0.9%	-9.4%	11.1%	0.863
Month 06	123	109	88.6%	68	63	92.6%	-4.0%	-12.4%	4.3%	0.373
Month 12	124	109	87.9%	64	58	90.6%	-2.7%	-11.9%	6.4%	0.575
Month 24	116	109	94.0%	59	52	88.1%	5.8%	-3.5%	15.1%	0.179

*Device group differences, Nominal 95% CI, and two-sided asymptotic p-value.
Restricted to subjects with baseline VAS Right Arm of 20 points or greater.
Source: Tables Clinical Follow-up.sas; Analyzed: 08JUL2026

VAS Left Arm/Shoulder Pain

Table 82 describes the mean VAS – Left Shoulder/Arm Pain score for the mITT Analysis Set over time through Month 24. In the investigational group, the mean VAS – Left Shoulder/Arm Pain score decreased from 56.1 at screening to 9.6 at Month 24. In the control group, the mean VAS– Left Shoulder/Arm Pain score decreased from 53.5 at screening to 6.1 at Month 24.

Table 82 VAS Pain (Left Shoulder/Arm) values over time (mITT Analysis Set, n=309)

	BAGUERA® C						Control						Group Difference	
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	Diff.	p*
Screening	210	56.2	33.8	68.5	0.0	100.0	98	53.5	36.2	66.0	0.0	100.0	2.7	0.271
Week 06	208	13.2	21.6	3.0	0.0	97.0	93	11.6	17.8	3.0	0.0	85.0	1.6	0.441
Month 03	204	9.5	17.8	1.0	0.0	90.0	94	11.1	17.0	2.5	0.0	86.0	-1.6	0.051
Month 06	201	10.6	21.9	0.0	0.0	100.0	93	11.3	19.7	1.0	0.0	80.0	-0.7	0.223
Month 12	201	9.4	18.5	0.0	0.0	94.0	89	8.8	18.3	1.0	0.0	100.0	0.7	0.397
Month 24	189	9.6	18.4	0.0	0.0	86.0	82	6.1	12.1	0.0	0.0	59.0	3.5	0.410

*Two-sided 95% Wilcoxon Rank Sum test.
Source: Tables Clinical Follow-up.sas; Analyzed: 08JUL2026

Table 83 identifies the number and percentage of subjects showing an improvement in VAS – Left Shoulder/Arm Pain score greater than 20 points as compared to all subjects in the study at each follow up time point for both the investigational and control groups. At Month 24, 91.4% (128/140) of investigational subjects achieved greater than a 20-point improvement in VAS – Left Shoulder/Arm Pain score as compared to baseline, while 95.2% (60/63) of control subjects achieved greater than a 20-point improvement in VAS – Left Shoulder/Arm Pain score as compared to baseline.

Table 83 VAS Left Shoulder/Arm Pain 20-Point Responder (mITT Analysis Set, n=309)

	BAGUERA® C			Control			Group Difference*			
	N	n	%	N	n	%	Δ	LB	UB	p
Week 06	155	143	92.3%	70	62	88.6%	3.7%	-4.9%	12.2%	0.368
Month 03	152	138	90.8%	70	63	90.0%	0.8%	-7.6%	9.2%	0.852
Month 06	149	134	89.9%	70	62	88.6%	1.4%	-7.5%	10.2%	0.759
Month 12	150	135	90.0%	67	61	91.0%	-1.0%	-9.4%	7.3%	0.810
Month 24	140	128	91.4%	63	60	95.2%	-3.8%	-10.8%	3.2%	0.337

*Device group differences, Nominal 95% CI, and two-sided asymptotic p-value.
Restricted to subjects with baseline VAS Left Arm of 20 points or greater.
Source: Tables Clinical Follow-up.sas; Analyzed: 08JUL2026

Dysphagia Handicap Index

DHI was administered to subjects in order to assess swallowing difficulties. As Table 84 reports, in the investigational group, the pre-operative DHI mean score was 8.0, and dropped post-operatively to a Month 24 DHI mean score of 4.2. Similarly, in the control group, the pre-operative DHI mean score was 10.1, and also dropped post-operatively to a Month 24 DHI mean score of 3.0. This suggests that as a whole, both the investigational and control treatments do not significantly contribute to development of swallowing difficulties.

Table 84 DHI Scores over time (mITT analysis set N=309)

	BAGUERA® C						Control						Group Difference	
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	Diff.	p*
Screening	210	8.0	12.3	4.0	0.0	70.0	98	10.1	15.3	4.0	0.0	92.0	-2.1	0.134
Week 06	205	7.4	11.1	2.0	0.0	64.0	93	7.1	9.6	4.0	0.0	42.0	0.2	0.246
Month 03	204	5.4	10.0	0.0	0.0	56.0	93	5.4	8.9	2.0	0.0	42.0	0.0	0.317
Month 06	200	4.6	9.0	0.0	0.0	60.0	93	3.7	6.5	0.0	0.0	38.0	0.8	0.452
Month 12	201	4.6	8.7	0.0	0.0	48.0	89	3.8	5.9	0.0	0.0	30.0	0.8	0.341
Month 24	187	4.2	9.0	0.0	0.0	58.0	82	3.0	5.6	0.0	0.0	30.0	1.2	0.463

*Two-sided 95% Wilcoxon Rank Sum test.
Source: Tables Clinical Follow-up.sas; Analyzed: 08JUL2026

Short-Form (SF-12v2) – Physical Component Score (PCS)

The results of the PCS portion of the SF-12v2 are shown in Table 85**.** In the investigational group, the pre-operative SF-12v2 PCS mean score was 32.2 and increased post-operatively to a Month 24 SF-12v2 PCS mean score of 41.6. Similarly, in the control group, the pre-operative SF-12v2 PCS mean score was 32.6, and also increased post-operatively to a Month 24 SF-12v2 PCS mean score of 42.3.

Table 85 SF-12 (PCS) score over time (mITT analysis set, N=309)

	BAGUERA® C						Control						Group Difference	
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	Dif	p*
Screening	209	32.2	6.4	32.0	16.1	47.6	98	32.6	5.8	32.9	16.7	42.8	-0.4	0.223
Month 06	197	37.9	4.8	37.8	24.2	51.6	93	38.1	4.8	37.8	24.1	52.2	-0.2	0.401
Month 12	201	38.2	4.9	37.8	23.4	59.5	89	37.8	5.1	37.8	18.9	49.6	0.4	0.485
Month 24	187	41.6	7.1	39.5	26.1	61.7	82	42.3	6.9	40.9	31.5	62.2	-0.6	0.227

*Two-sided 95% Wilcoxon Rank Sum test.
Source: Tables Clinical Follow-up.sas; Analyzed: 08JUL2026

Short-Form (SF-12v2) – Mental Component Score (MCS)

The results of the MCS portion of the SF-12v2 are shown in Table 86. In the investigational group, the pre-operative SF-12v2 MCS mean score was 46.0, and increased post-operatively to a Month 24 SF-12v2 MCS mean score of 56.5. Similarly, in the control group, the pre-operative SF-12v2 MCS mean score was 44.2, and also increased post-operatively to a Month 24 SF-12v2 MCS mean score of 57.1.

Table 86 SF-12 (MCS) values over time (mITT analysis set, N=309)

	BAGUERA® C						Control						Group Difference	
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	Dif	p*
Screening	209	46.0	12.9	46.6	16.3	74.6	98	44.2	13.0	44.6	18.1	72.9	1.9	0.133
Month 06	197	57.9	10.5	61.9	18.2	71.1	93	56.6	10.3	58.8	27.8	70.3	1.4	0.105
Month 12	201	58.3	10.7	62.2	26.6	72.4	89	57.0	9.5	59.5	35.9	71.1	1.4	0.051
Month 24	187	56.5	10.1	57.9	23.2	70.9	82	57.1	9.3	58.1	32.1	71.1	-0.6	0.420

*Two-sided 95% Wilcoxon Rank Sum test.
Source: Tables Clinical Follow-up.sas; Analyzed: 08JUL2026

Odom's Criteria

Odom's Criteria consist of a 4-point rating scale for surgeons to assess clinical outcomes following cervical spine surgery. Table 87 provides the ratings for Odom's Criteria at Month 24. In both groups, the predominant response is "Excellent" or "Good" at Month 24. At Month 24, a response of "Excellent" or "Good" was reported in 98.4% (185/188) of investigational cases, and similarly, a response of "Excellent" or "Good" was reported in 100% (83/83) of control cases.

Table 87 Odom's criteria (mITT analysis set, N=309)

	Month 24			
	BAGUERA® C		Control	
	n	%	n	%
Excellent	161	86%	73	88%
Good	24	13%	10	12%
Fair	2	1%	0	0%
Poor	1	1%	0	0%

Subjects censored at Index level secondary surgical interventions.
Source: Tables Clinical Follow-up.sas; Analyzed: 08JUL2026

Patient Satisfaction

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

Table 88 presents the subject responses for both the BAGUERA® C investigational group and the Mobi-C control group to the survey question, "How satisfied are you with the overall result of your surgery?". The response options included "Very Satisfied", "Somewhat Satisfied", "Neither Satisfied nor Dissatisfied", "Somewhat Dissatisfied" and "Very Dissatisfied". A total 88.9% (168/189) of investigational subjects reported that they were "Very Satisfied" at Month 24, as compared to a total of 86.6% (71/82) of control subjects expressing this perspective at Month 24. 2.1% (4/189) of subjects in

the investigational group reported being "Somewhat Dissatisfied" or "Very Dissatisfied" at Month 24 as compared to 1.2% (1/82) of control subjects

Table 88 Treatment Satisfaction:
"How satisfied are you with the overall result of your surgery?"
(mITT Analysis Set)

	Month 12				Month 24			
	BAGUERA® C		Control		BAGUERA® C		Control	
	n	%	n	%	n	%	n	%
Very Satisfied	170	85%	75	84%	168	89%	71	87%
Somewhat Satisfied	25	12%	11	12%	13	7%	9	11%
Neither Satisfied nor Dissatisfied	5	2%	1	1%	4	2%	1	1%
Somewhat Dissatisfied	1	0%	2	2%	3	2%	1	1%
Very Dissatisfied	0	0%	0	0%	1	1%	0	0%
Source: Tables Clinical Follow-up.sas; Analyzed: 08JUL2026								

Table 89 presents the subject responses to the survey question, "All things considered, would you have the surgery again?". The response options included "Definitely", "Probably", "Possibly", "Probably Not" and "Definitely Not". A total 86.8% (164/189) of investigational subjects answered "Definitely" at Month 24, as compared to a total of 84.1% (69/82) of control subjects expressing this perspective at Month 24. 2.6% (5/189) of subjects in the investigational group answered "Probably Not" or "Definitely Not" at Month 24 as compared to 2.4% (2/82) of control subjects.

Table 89 Treatment Satisfaction:
"All things considered, would you have the surgery again?"
(mITT Analysis Set)

	Month 12				Month 24			
	BAGUERA® C		Control		BAGUERA® C		Control	
	n	%	n	%	n	%	n	%
Definitely	170	85%	76	85%	164	87%	69	84%
Probably	22	11%	7	8%	15	8%	7	9%
Possibly	8	4%	5	6%	5	3%	4	5%
Probably Not	0	0%	1	1%	5	3%	2	2%
Definitely Not	1	0%	0	0%	0	0%	0	0%
Source: Tables Clinical Follow-up.sas; Analyzed: 08JUL2026								

Table 90 presents the subject responses to the survey question, "Would you recommend the surgery to a friend or family member?". The response options included "Definitely", "Probably", "Possibly", "Probably Not" and "Definitely Not". A total 88.4% (167/189) of investigational subjects answered "Definitely" at Month 24, as compared to a total of 86.6% (71/82) of control subjects expressing this perspective at Month 24. 1.6% (3/189) of subjects in the

investigational group answered "Probably Not" or "Definitely Not" at Month 24 as compared to 0.0% (0/82) of control subjects.

Table 90 Treatment Satisfaction:
"Would you recommend the surgery to a friend or family member?"
(mITT Analysis Set)

	Month 12				Month 24			
	BAGUERA® C		Control		BAGUERA® C		Control	
	n	%	n	%	n	%	n	%
Definitely	172	86%	78	88%	167	88%	71	87%
Probably	22	11%	8	9%	13	7%	8	10%
Possibly	6	3%	3	3%	6	3%	3	4%
Probably Not	0	0%	0	0%	3	2%	0	0%
Definitely Not	1	0%	0	0%	0	0%	0	0%
Source: Tables Clinical Follow-up.sas; Analyzed: 08JUL2026								

Radiographic Assessments - Quantitative

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 91 reports the angular motion of the index levels 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 91 Angular Motion (Index Levels) [degrees] (mITT Analysis Set, N=309)

SUPERIOR LEVEL														
	BAGUERA® C						Control						Group Difference	
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	Dif	p*
Screening	208	8.8	4.6	8.5	0.1	25.4	89	8.2	4.5	7.8	0.2	20.4	0.5	0.188
Week 06	199	8.3	3.6	8.1	0.4	19.6	90	8.5	3.6	8.4	0.2	21.5	-0.2	0.304
Month 03	203	10.3	4.0	10.1	0.3	22.5	93	9.8	3.8	9.7	2.8	20.8	0.5	0.165
Month 06	202	10.4	4.3	10.0	0.9	24.5	91	10.7	4.5	10.5	2.0	23.9	-0.3	0.304
Month 12	197	10.3	4.5	9.8	0.3	24.4	87	10.5	4.8	9.6	0.5	22.9	-0.2	0.484
Month 24	188	10.1	4.8	9.8	0.0	20.4	80	10.0	5.3	9.9	0.0	23.9	0.1	0.424
INFERIOR LEVEL														
	BAGUERA® C						Control						Group Difference	
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	Dif	p*
Screening	194	7.3	4.2	6.9	0.4	21.6	81	6.7	4.1	6.3	0.4	17.5	0.7	0.116
Week 06	184	7.8	4.1	7.6	0.0	17.7	77	7.1	3.8	6.8	0.3	16.3	0.6	0.120
Month 03	188	9.3	4.2	9.4	0.3	19.1	83	8.4	3.6	8.2	0.6	16.3	0.8	0.047
Month 06	183	9.5	4.5	9.9	0.3	20.8	81	9.5	4.2	9.3	0.3	17.9	0.0	0.485
Month 12	192	9.3	4.7	9.5	0.1	21.7	77	9.2	4.4	8.3	1.4	19.8	0.1	0.389
Month 24	182	9.1	4.9	8.8	0.1	21.3	74	9.1	4.6	8.9	0.5	21.8	0.0	0.477
*Two-sided 95% Wilcoxon Rank Sum test. Source: Tables Radiography - 2L.sas; Analyzed: 08JUL2026														

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 92 reports the translational motion of the index levels 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 92 Translational Motion (index levels) [mm] (mITT Analysis Set, N=309)

SUPERIOR LEVEL														
	BAGUERA® C						**Control**						**Group Difference**	
	N	**Mean**	**SD**	**Med**	**Min**	**Max**	**N**	**Mean**	**SD**	**Med**	**Min**	**Max**	**Dif**	**p***
Screening	208	1.1	0.6	0.9	0.0	2.9	89	1.0	0.7	0.9	0.0	3.8	0.0	0.204
Week 06	199	1.0	0.5	1.0	0.1	2.7	90	1.3	0.6	1.3	0.0	2.6	-0.2	<.001
Month 03	203	1.3	0.6	1.3	0.0	3.1	93	1.5	0.6	1.5	0.3	3.1	-0.2	0.014
Month 06	202	1.3	0.6	1.3	0.0	3.6	91	1.7	0.8	1.6	0.0	3.5	-0.3	<.001
Month 12	197	1.3	0.7	1.3	0.0	3.2	87	1.6	0.8	1.6	0.0	3.2	-0.3	0.002
Month 24	188	1.3	0.7	1.3	0.0	3.4	80	1.5	0.9	1.6	0.1	4.6	-0.2	0.053
INFERIOR LEVEL														
	N	**Mean**	**SD**	**Med**	**Min**	**Max**	**N**	**Mean**	**SD**	**Med**	**Min**	**Max**	**Dif**	**p***
Screening	194	0.6	0.5	0.5	0.0	2.1	81	0.6	0.4	0.4	0.0	2.1	0.1	0.078
Week 06	184	0.9	0.5	0.8	0.0	2.4	77	0.9	0.6	0.9	0.0	2.6	0.0	0.402
Month 03	188	1.0	0.5	1.0	0.0	2.7	83	1.0	0.5	0.9	0.1	2.7	0.0	0.328
Month 06	183	1.1	0.6	1.0	0.0	2.7	81	1.2	0.7	1.1	0.0	3.7	-0.1	0.161
Month 12	192	1.0	0.6	1.0	0.0	2.9	77	1.1	0.6	1.0	0.1	2.9	-0.1	0.236
Month 24	182	1.0	0.6	0.9	0.0	2.9	74	1.1	0.7	1.0	0.0	3.6	-0.1	0.365

*Two-sided 95% Wilcoxon Rank Sum test.
Source: Tables Radiography - 2L.sas; Analyzed: 08JUL2026

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 93 reports the average disc height over time at the index levels. The mean average disc height increased post-operatively in both groups and was maintained over time. The mean average disc height at the superior level was calculated as 5.5mm in the investigational group and 5.2mm in the control group at Month 24. The mean average disc height at the inferior level increased post-operatively in both groups and was maintained over time. The mean average disc height was found to be 5.4mm in the investigational group and 5.1mm in the control group at Month 24.

Table 93 Average Disc Height [mm] over time (mITT Analysis Set, N=309)

SUPERIOR LEVEL														
	BAGUERA® C						Control						Group Difference	
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	Dif	p*
Screening	207	3.2	0.8	3.1	1.1	5.5	93	3.0	0.8	3.0	1.1	5.1	0.2	0.026
Post-Operative / Discharge	192	6.0	0.8	5.9	4.1	9.7	89	5.8	0.6	5.8	4.1	7.2	0.2	0.062
Week 06	207	5.6	0.7	5.6	3.5	7.7	96	5.3	0.7	5.3	3.4	7.0	0.3	<.001
Month 03	205	5.6	0.7	5.6	3.5	7.8	92	5.3	0.7	5.3	2.8	6.9	0.3	<.001
Month 06	202	5.6	0.7	5.6	3.5	7.8	93	5.2	0.7	5.2	2.7	6.8	0.3	<.001
Month 12	197	5.5	0.7	5.5	2.7	7.2	89	5.2	0.7	5.3	2.5	7.0	0.3	<.001
Month 24	185	5.5	0.7	5.5	2.7	7.2	81	5.2	0.7	5.3	2.6	6.8	0.3	0.002
INFERIOR LEVEL														
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	Dif	p*
Screening	197	3.2	0.7	3.1	1.5	5.4	89	3.1	0.8	3.2	1.3	5.3	0.0	0.449
Post-Operative / Discharge	113	5.9	0.7	5.8	3.9	8.0	56	5.8	0.8	5.8	4.3	7.4	0.1	0.271
Week 06	199	5.5	0.7	5.6	2.9	7.5	89	5.1	0.7	5.1	3.0	7.2	0.4	<.001
Month 03	197	5.5	0.7	5.6	2.9	7.5	87	5.1	0.7	5.1	3.3	7.1	0.4	<.001
Month 06	199	5.5	0.7	5.5	2.9	7.5	87	5.1	0.7	5.1	3.4	7.1	0.4	<.001
Month 12	194	5.4	0.7	5.5	2.9	7.4	84	5.1	0.7	5.0	3.3	7.0	0.4	<.001
Month 24	182	5.4	0.7	5.5	3.0	7.3	79	5.1	0.7	5.1	3.2	7.1	0.3	<.001

*Two-sided 95% Wilcoxon Rank Sum test.
Source: Tables Radiography - 2L.sas; Analyzed: 08JUL2026

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 94 reports the disc angle over time at the index levels. The mean disc angle at the superior level increased post-operatively in both groups and was maintained over time. The mean disc angle was calculated as 7.5 degrees in the investigational group and 7.9 degrees in the control group at Month 24. The mean disc angle at the inferior level increased post-operatively in both groups and was maintained over time. The mean disc angle at the inferior level was found to be 6.3 degrees in the investigational group and 5.6 degrees in the control group at Month 24.

Table 94 Disc Angle [degrees] over time (mITT Analysis Set, N=309)

SUPERIOR LEVEL														
	BAGUERA® C						Control						Group Difference	
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	Dif	p*
Screening	207	2.3	4.1	2.1	-8.3	14.4	93	2.6	3.8	2.2	-6.5	13.9	-0.2	0.253
Post-Operative / Discharge	192	9.4	3.4	9.5	-0.7	18.4	89	9.8	3.5	9.4	0.5	19.4	-0.4	0.268
Week 06	207	7.6	4.6	7.5	-5.6	19.3	96	8.0	4.4	7.5	-7.9	18.2	-0.4	0.293
Month 03	205	7.7	4.7	7.7	-6.2	20.3	92	8.0	4.3	8.0	-0.2	16.8	-0.3	0.370
Month 06	202	7.6	4.8	7.8	-4.7	20.5	93	8.2	4.4	7.3	-0.1	18.1	-0.6	0.247
Month 12	197	7.4	4.7	7.5	-3.1	21.6	89	8.2	4.4	8.2	-1.3	18.0	-0.9	0.076
Month 24	185	7.5	4.6	7.9	-3.5	22.0	81	7.9	4.6	7.6	-0.2	18.6	-0.4	0.341
INFERIOR LEVEL														
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	Dif	p*
Screening	197	2.8	3.5	2.6	-5.8	11.5	89	2.9	3.7	2.2	-6.8	12.8	-0.1	0.472
Post-Operative / Discharge	113	10.9	4.6	10.8	2.3	23.7	56	10.5	5.2	10.5	-0.8	19.6	0.3	0.391
Week 06	199	6.0	4.2	6.1	-4.7	18.1	89	5.5	4.4	5.0	-4.4	18.4	0.5	0.175
Month 03	197	6.1	4.1	6.1	-3.9	16.8	87	5.6	4.5	5.3	-4.8	18.8	0.4	0.212
Month 06	199	5.9	4.2	6.0	-5.5	18.1	87	5.8	4.8	6.1	-5.4	17.5	0.2	0.409
Month 12	194	6.0	4.1	5.9	-5.5	16.8	84	5.7	4.9	5.6	-5.8	17.8	0.3	0.226
Month 24	182	6.3	3.9	6.1	-4.1	17.0	79	5.6	4.9	5.1	-5.4	16.6	0.7	0.087

*Two-sided 95% Wilcoxon Rank Sum test.
Source: Tables Radiography - 2L.sas; Analyzed: 08JUL2026

Radiographic Assessments - Qualitative

Device Condition

Based upon the radiographic data, device condition was assessed at each timepoint. **Table 95** identifies the device condition classification at the index levels in both groups. All devices at the superior level in both groups were assessed to be intact (i.e., no evidence of device disassembly, fracture, or loosening). All devices at the inferior level in both groups were assessed to be intact (i.e., no evidence of device disassembly, fracture, or loosening). In one case for the control arm, 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 95 Device Condition – mITT Analysis Set, N=309

SUPERIOR LEVEL																
	Month 03				Month 06				Month 12				Month 24			
	BAGUERA® C		Control		BAGUERA® C		Control		BAGUERA® C		Control		BAGUERA® C		Control	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Intact	205	100%	94	100%	202	100%	93	100%	197	100%	89	100%	188	100%	82	100%
Disassembled	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Fractured	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Loose	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Indeterminate	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Unable to assess	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Not Applicable	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Not Required	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
INFERIOR LEVEL																
	Month 03				Month 06				Month 12				Month 24			
	BAGUERA		Control		BAGUERA		Control		BAGUERA		Control		BAGUERA		Control	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Intact	205	100%	93	99%	202	100%	92	99%	197	100%	88	99%	188	100%	82	100%
Disassembled	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Fractured	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Loose	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Indeterminate	0	0%	1	1%	0	0%	1	1%	0	0%	1	1%	0	0%	0	0%
Unable to assess	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Not Applicable	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Not Required	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Source: Tables Radiography - 2L.sas; Analyzed: 08JUL2026																

Device Migration

Based upon the radiographic data, device migration was assessed at each timepoint. As presented in Table 96 below, all devices at the superior level in both groups were assessed to have no evidence of migration, with the exception of one (1) control device detected to have migrated (i.e., presence of AP or lateral change in implant position greater than or equal to 3mm) at Month 3 through Month 24. All devices at the inferior level in both groups were assessed to

have no evidence of migration, although there was one case at Month 3 through Month 12 in the control group that was indeterminate or could not be assessed.

Table 96 Device Migration – (mITT Analysis Set, N=309)

SUPERIOR LEVEL																
	Month 03				**Month 06**				**Month 12**				**Month 24**			
	BAGUERA® C		**Control**		**BAGUERA® C**		**Control**		**BAGUERA® C**		**Control**		**BAGUERA® C**		**Control**	
	n	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Absent	205	100%	93	99%	202	100%	92	99%	197	100%	88	99%	188	100%	81	99%
Present - Migration	0	0%	1	1%	0	0%	1	1%	0	0%	1	1%	0	0%	1	1%
Present - Extrusion	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Indeterminate	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Unable to assess	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Not Applicable	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Not Required	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
INFERIOR LEVEL																
	BAGUERA® C		**Control**		**BAGUERA® C**		**Control**		**BAGUERA® C**		**Control**		**BAGUERA® C**		**Control**	
	n	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Absent	205	100%	93	99%	202	100%	92	99%	197	100%	88	99%	188	100%	82	100%
Present - Migration	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Present - Extrusion	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Indeterminate	0	0%	1	1%	0	0%	1	1%	0	0%	1	1%	0	0%	0	0%
Unable to assess	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Not Applicable	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Not Required	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Source: Tables Radiography - 2L.sas; Analyzed: 08JUL2026																

Device Subsidence

Based upon the radiographic data, device subsidence was evaluated at each timepoint from Month 3 to Month 24 (see Table 97 below). All 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 2mm). Similarly, all devices at the inferior level in both groups were assessed to have no evidence of subsidence.

Table 97 Device Subsidence (mITT Analysis Set, N=309)

SUPERIOR LEVEL																
	Month 03				Month 06				Month 12				Month 24			
	BAGUERA® C		Control		BAGUERA® C		Control		BAGUERA® C		Control		BAGUERA® C		Control	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Absent	205	100%	94	100%	202	100%	93	100%	197	100%	89	100%	188	100%	82	100%
Cranial/Caudal Subsidence > 2 mm	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Indeterminate	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Unable to assess	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Not Applicable	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Not Required	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
INFERIOR LEVEL																
	BAGUERA® C		Control		BAGUERA® C		Control		BAGUERA® C		Control		BAGUERA® C		Control	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Absent	205	100%	93	99%	202	100%	92	99%	197	100%	88	99%	188	100%	82	100%
Cranial/Caudal Subsidence > 2 mm	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Indeterminate	0	0%	1	1%	0	0%	1	1%	0	0%	1	1%	0	0%	0	0%
Unable to assess	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Not Applicable	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Not Required	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Source: Tables Radiography - 2L.sas; Analyzed: 29JUN2026																

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 98 identifies the findings related to HO at each timepoint at the index levels. There is increasing progression of HO over time at the superior level, with Class II HO being the predominant type at later timepoints. A total of 54% (102/188) of investigational devices and 66% (54/82) of control devices were assessed to have Class II HO at Month 24. Similarly, there is increasing progression of HO over time at the inferior level, with Class II HO being the predominant type at later timepoints. A total of 49% (91/186) of investigational devices and 66% (53/80) of control devices were assessed to have Class II HO at Month 24.

Table 98 Heterotopic Ossification (mITT Analysis Set, N=309)

SUPERIOR LEVEL																
	Month 03				**Month 06**				**Month 12**				**Month 24**			
	BAGUERA® C		**Control**		**BAGUERA® C**		**Control**		**BAGUERA® C**		**Control**		**BAGUERA® C**		**Control**	
	n	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
None	196	96%	84	89%	171	85%	68	73%	106	54%	37	42%	50	27%	11	13%
Class I	4	2%	1	1%	12	6%	1	1%	23	12%	2	2%	16	9%	1	1%
Class II	5	2%	9	10%	19	9%	24	26%	61	31%	44	49%	102	54%	54	66%
Class III	0	0%	0	0%	0	0%	0	0%	6	3%	5	6%	17	9%	15	18%
Class IV	0	0%	0	0%	0	0%	0	0%	1	1%	1	1%	3	2%	1	1%
Indeterminate	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Unable to assess	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Not Applicable	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Not Required	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
INFERIOR LEVEL																
None	189	94%	88	95%	162	81%	75	82%	102	53%	37	43%	47	25%	13	16%
Class I	4	2%	2	2%	8	4%	2	2%	21	11%	4	5%	20	11%	1	1%
Class II	9	4%	3	3%	29	15%	13	14%	63	32%	40	46%	91	49%	53	66%
Class III	0	0%	0	0%	1	1%	0	0%	8	4%	4	5%	25	13%	9	11%
Class IV	0	0%	0	0%	0	0%	1	1%	0	0%	2	2%	3	2%	4	5%
Indeterminate	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Unable to assess	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Not Applicable	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Not Required	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Source: Tables Radiography - 2L.sas; Analyzed: 29JUN2026																

Adjacent level Disc Degeneration (Kellgren-Lawrence)

Based upon the radiographic data, adjacent level disc degeneration (ALDD) was evaluated at Month 12 and Month 24. 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 99 reports the findings related to ALDD at each timepoint at the index levels. At the superior level, there is an increase in ALDD over time in both groups. However, 0% of investigational subjects and 1% (1/82) of control subjects are classified to have severe ALDD at Month 24. At the inferior level, there is an increase in ALDD over time in both groups. However, no subject in either group was classified to have severe ALDD at Month 24, with the caveat that 23% (43/188) of investigational devices and 27% (22/82) of control devices at Month 24 were categorized as indeterminate.

Table 99 Adjacent Level DD (mITT Analysis Set, N=309)

SUPERIOR LEVEL								
	Month 12				**Month 24**			
	BAGUERA® C		**Control**		**BAGUERA® C**		**Control**	
	n	**%**	**n**	**%**	**n**	**%**	**n**	**%**
None	105	53%	41	46%	71	38%	29	35%
Doubtful	51	26%	29	33%	62	33%	28	34%
Minimal	32	16%	17	19%	43	23%	23	28%
Moderate	8	4%	1	1%	12	6%	1	1%
Severe	1	1%	1	1%	0	0%	1	1%
Indeterminate	0	0%	0	0%	0	0%	0	0%
Unable to assess	0	0%	0	0%	0	0%	0	0%
Not Applicable	0	0%	0	0%	0	0%	0	0%
Not Required	0	0%	0	0%	0	0%	0	0%
INFERIOR LEVEL								
	Month 12				**Month 24**			
	BAGUERA® C		**Control**		**BAGUERA® C**		**Control**	
	n	**%**	**n**	**%**	**n**	**%**	**n**	**%**
None	117	59%	48	54%	102	54%	39	48%
Doubtful	24	12%	13	15%	22	12%	10	12%
Minimal	7	4%	4	4%	12	6%	8	10%
Moderate	5	3%	3	3%	7	4%	2	2%
Severe	1	1%	0	0%	0	0%	0	0%
Indeterminate	42	21%	21	24%	43	23%	22	27%
Unable to assess	1	1%	0	0%	2	1%	1	1%
Not Applicable	0	0%	0	0%	0	0%	0	0%
Not Required	0	0%	0	0%	0	0%	0	0%
Source: Tables Radiography - 2L.sas; Analyzed: 29JUN2026								

Subgroup Analyses

The study was not specifically powered for any subgroup analyses.

Pediatric Extrapolation

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

c) 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 91 investigators of which none were full-time or part-time employees of the sponsor and ten clinical investigators had disclosable financial interests/arrangements as defined in sections 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: One
- Significant payment of other sorts: Nine
- Proprietary interest in the product tested held by the investigator: None
- Significant equity interest held by investigator in sponsor of covered study: None

The applicant 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.

XI. PANEL MEETING RECOMMENDATION AND FDA'S POST-PANEL ACTION

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 was not referred to the Orthopaedic and Rehabilitation Devices Panel, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

XII. CONCLUSIONS DRAWN FROM PRECLINICAL AND CLINICAL STUDIES

The valid scientific evidence presented in the preceding sections provides reasonable assurance that the BAGUERA® C Cervical Disc Prosthesis is a safe and effective disc replacement in skeletally mature patients for reconstruction of the disc at one- or two-contiguous levels from C3-C7 following discectomy for intractable radiculopathy (arm pain and/or a neurological deficit) with or without neck pain, or myelopathy due to abnormality localized to the disc space and manifested by at least one of the following conditions confirmed by radiographic imaging (e.g., X-rays, computed tomography (CT), magnetic resonance imaging (MRI)): herniated nucleus pulposus, spondylosis (defined by the presence of osteophytes), and/or visible loss of disc height as compared to adjacent levels.

A. Effectiveness Conclusions

Single-Level Study:

In the prospective, multi-center, randomized, controlled clinical study to support PMA approval of the BAGUERA® C Cervical Disc Prosthesis for use at a single level, success was achieved in the primary CCS 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 serious adverse event(s) confirmed as device or procedure related as adjudicated by the CEC. One hundred eighty-nine (189) subjects were treated with the investigational device and ninety-six (96) subjects were treated with the control device. The imputed overall success rate for the investigational group was 89.0% as compared to a success rate of 89.8% for the control group. The study's pre-specified success criterion required this probability to exceed 95% to declare success, which was achieved in this analysis.

A secondary supporting sensitivity analysis of the primary endpoint was performed considering only subjects with Month 24 observed data. The results were similar, with a success rate of 89.0% (161/181) as compared to a success rate of 89.4% (76/85) for the control group.

Therefore, non-inferiority between the investigational and control groups was demonstrated.

Two-Contiguous Level Study

In the prospective, multi-center, randomized, controlled clinical study to support PMA approval of the BAGUERA® C Cervical Disc Prosthesis for use at two contiguous levels, success was achieved in the primary CCS 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 serious adverse event(s) confirmed as device or procedure related as adjudicated by the CEC. Two hundred nine (209) subjects were treated with the investigational device and ninety-eight (98) subjects were treated with the control device. The imputed overall success rate for the investigational group was 90.0% as compared to a success rate of 93.0% for the control group. The study's pre-specified success criterion required this probability to exceed 95% to declare success, which was achieved in this analysis.

A secondary supporting sensitivity analysis of the primary endpoint was performed considering only subjects with Month 24 observed data. The results were similar, with a success rate of 90.6% (174/192) as compared to a success rate of 94.1% (80/85) for the control group.

Therefore, non-inferiority between the investigational and control groups was demonstrated.

In conclusion, the study data indicate that at Month 24, the BAGUERA® C Cervical Disc Prosthesis is at least as effective as the Mobi-C (control), for the patient populations and indications studied in these investigations, in terms of overall success according to the primary composite endpoint and provides a reasonable assurance of effectiveness.

B. Safety Conclusions

In the clinical studies conducted to support PMA approval, the investigational BAGUERA® C Cervical Disc Prosthesis demonstrated a reasonable assurance of safety compared to the control cervical disc arthroplasty (Mobi-C® Cervical Disc).

In the single-level study, in the AT analysis set, comparable AE rates were observed in the investigational group (61.9% - 117/189) and control group (69.8% - 67/96). SAEs that were considered “definitely” device-related were also comparable between the two groups, where 0% (0/189) of investigational subjects had “definitely” device-related SAEs, while 2.1% (2/96) of control subjects had “definitely” device-related SAEs. A total of seven (7) subjects within 24 months experienced an SSI in the investigational group, while three (3) subjects had an SSI in the control group.

In the two-contiguous-level study, in the AT analysis set, comparable AE rates of AEs occurred in the investigational group (65.7% - 138/210) and control group (59.2% - 58/98). SAEs that were considered “definitely” device-related were also comparable between the two groups, where 0.5% (1/210) of investigational subjects had “definitely” device-related SAEs, while 1.0% (1/98) control subjects had

"definitely" device-related SAEs. A total of six (6) subjects experienced an SSI in the investigational group, while four (4) subjects had an SSI in the control group.

In conclusion, the clinical study results demonstrate that the BAGUERA® C Cervical Disc Prosthesis is at least as safe as the Mobi-C® Cervical Disc control and that the device has a reasonable assurance of safety.

C. Benefit-Risk Conclusions

The probable benefits of the BAGUERA® C Cervical Disc Prosthesis are based on data collected in the clinical studies conducted to support PMA approval as described above.

The clinical studies demonstrated several benefits of the BAGUERA® C Cervical Disc Prosthesis at one and two contiguous cervical levels over the 24-month time period studied. Table 100 below also describes evaluation of benefits:

Table 100 Benefit-Risk Evaluation

		1-level replacement	2-level replacement
Benefits	The benefit of the subject device was evaluated in terms of clinically meaningful improvement in function (as measured by an improvement in NDI of at least 15 points) at Month 24.	The investigational subjects experienced a comparable level of NDI improvement (92.1% - 163/177) as compared to the control subjects (94% - 79/84) at Month 24.	The investigational subjects experienced a comparable level of NDI improvement (94.7% - 179/189) as compared to the control subjects (98.8% - 81/82) at Month 24.
	The benefit of the subject device was evaluated 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.	The investigational subjects demonstrated a comparable level of change (87.0% - 147/169) as compared to control subjects (88.9% - 72/81).	The investigational subjects demonstrated a comparable level of change (94.6% - 176/186) as compared to control subjects (92.6% - 75/81).
	The benefit of the subject device was evaluated in terms of improvement in right shoulder/arm pain (as measured by a 20mm improvement in pain on a 100mm VAS as compared to baseline) at Month 24.	The investigational subjects demonstrated a comparable level of change (90.0% - 99/110) as compared to control subjects (93.6% - 44/47).	The investigational subjects demonstrated a comparable level of change (94.0% - 109/116) as compared to control subjects (88% - 52/59).
	The benefit of the subject device was evaluated in terms of improvement in left shoulder/arm pain (as measured by a 20mm improvement in pain on a 100mm VAS as compared to baseline) at Month 24.	The investigational subjects demonstrated a comparable level of change (91.1% - 113/124) as compared to control subjects (98.4% - 61/62).	The investigational subjects demonstrated a comparable level of change (91.4% - 128/140) as compared to control subjects (95.2% - 60/63).

		1-level replacement	2-level replacement
	The subject's perception of their benefit and risk was indirectly measured by administering the question, "How satisfied are you with the outcome of the surgery?"	A total of 80.2% (142/177) of investigational subjects and 88.1% (74/84) of control subjects responded that they were "very satisfied", indicating a comparable level of positive response from the patient perspective regarding the operative procedure.	A total of 88.9% (168/189) of investigational subjects and 86.6% (71/82) of control subjects responded that they were "very 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 the clinical studies conducted to support PMA approval. The investigational group experienced comparable AE and SAE rates as compared to the control group as described above. In the single-level IDE study , a total of seven (7) subjects experienced an SSI in the investigational group, while three (3) subjects had an SSI in the control group; this is comparable given the nearly double sample size in the investigational group. In the two contiguous-level IDE study, a total of six (6) subjects experienced an SSI in the investigational group, while four (4) subjects had an SSI in the control group; this is comparable given the nearly double sample size in the investigational group.

Several additional factors were considered in determination of the probable benefits and risks for the BAGUERA® C Cervical Disc Prosthesis used at one or two contiguous levels. Limitations of the clinical study design included lack of subject masking with regard to treatment assignment, reliance on subjective endpoints, subjectivity regarding adverse event classification, and lack of power to study effects of treatment in subgroups. The impact of missing data and the robustness of the sensitivity analyses provided to address the missing data, as well as the generalizability of the study results were also considered. Alternative available treatments and risk mitigation strategies were considered, as was the fact that the only available indicator of subject tolerance for risk and perspective on benefit was subject satisfaction data.

Patient perspectives considered during this review include: NDI, VAS – Neck Pain, VAS – Left Arm Pain, VAS – Right ARM Pain, SF-12 PCS and MCS.

In conclusion, given the available information above, the data support that, for reconstruction of the disc at a single or two-contiguous levels from C3-C7 following single-level or two-contiguous-level discectomy for intractable radiculopathy (arm pain and/or a neurological deficit) with or without neck pain, or myelopathy due to a single-level or two-contiguous-level abnormality localized to the disc space and manifested by at least one of the following conditions confirmed by radiographic imaging (e.g., X-rays, computed tomography (CT), magnetic

resonance imaging (MRI)): 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 BAGUERA® C Cervical Disc Prosthesis outweigh the probable risks through Month 24.

D. Overall Conclusions

The non-clinical and clinical data in this application support the reasonable assurance of safety and effectiveness of the BAGUERA® C Cervical Disc Prosthesis 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 BAGUERA® C Cervical Disc Prosthesis in terms of improvement in pain and disability, outweigh the risks, both in terms of the risks associated with the BAGUERA® C Cervical Disc Prosthesis and surgical procedure when used in the indicated population in accordance with the directions for use, and as compared to the cervical disc arthroplasty control treatment in the same indicated population.

XIII. CDRH DECISION

CDRH issued an approval order on August 10, 2026. The final clinical conditions of approval cited in the approval order are described below.

Based on the protocol outline received on August 3, 2026, this PAS will be a continued follow-up of the PMA for the BAGUERA ® C Cervical Disc Prosthesis intended to evaluate the longer-term safety and effectiveness in the one-level study (n=189 BAGUERA ® C Cervical Disc Prothesis subjects) and two-contiguous-level study (n=209 BAGUERA ® C Cervical Disc Prothesis subjects) available from the Per Protocol Analysis Set who were enrolled in the pivotal study. Subjects will be followed 60 months from the time of each subject's index surgery (Month 60).

The primary safety endpoints are serious adverse events (SAEs), and device- or procedure-related Adverse Events (AEs). Additional safety analyses will include the rate of AEs, including by relatedness to device or procedure and severity (mild, moderate, or severe), time-to-event, including mean and ranges if applicable, and Subsequent Surgical Intervention (SSI) by rate and type.

The primary effectiveness endpoint is a composite clinical success (CCS) responder endpoint based on clinical status at Month 60. An individual subject will be regarded as achieving Month 60 CCS only if they meet all of the following criteria at Month 60 compared to baseline:

- Improvement in pain and function, as measured through the Neck Disability Index (NDI), of at least 15 percentage points (out of 100%) compared to pre-operative assessment;
- Maintenance or improvement in neurologic status at 60 months compared to baseline (as determined by the CEC);
- No secondary surgical intervention defined as revision, removal, reoperation, or supplemental fixation at the index level;
- No serious adverse event(s) confirmed as device or procedure related (as determined by the CEC).

The data presentation and statistical analyses will be conducted using observed data on a minimum of 85% follow-up of the pivotal study cohort at 36-months, 48-months, and 60-months post-implantation.

Additionally, an analysis of explanted BAGUERA ® C devices from the PAS population will be provided in the post-approval study annual reports for a period of 60 months (from the time of the initial implantation procedure) including the following information or an explanation why certain information is not available: a detailed clinical narrative, a copy of the operative report from the original index surgery, copies of operative reports from all subsequent surgeries including the removal surgery, copies of any available histologic analyses of the host response to the device and any particulate debris conducted by an independent laboratory (or the hospital where the device was removed if the surgeon did not send the sample to the independent laboratory) for explants in the United States, and any available explant analysis including a detailed explant analysis conducted by an independent laboratory.

The applicant's manufacturing facility was inspected and found to be in compliance with the device Quality System (QS) regulation (21 CFR 820), which was in effect at the time of the inspection. As of February 2, 2026, the revised part 820, referred to as the Quality Management System Regulation (QMSR), is effective.

XIV. APPROVAL SPECIFICATIONS

Directions for use: See device labelling.

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.