Clinical Evaluation Summary (CES)

Device Name: ABC Knee Assist Orthotic System
Device Classification: Class II Medical Device (US FDA 21 CFR 888.3470 / EU MDR Class IIa, Rule 1)
Target Population: Adult patients (aged ≥ 45 years) diagnosed with mild-to-moderate medial compartment knee osteoarthritis (Kellgren-Lawrence Grade II or III)
Intended Use: Unloading, stabilization, and biomechanical support of the knee joint to alleviate pain and improve functional mobility during weight-bearing activities.

1. Comprehensive Device Description

The ABC Knee Assist Orthotic System is a lightweight, active-assist external wearable orthotic device designed to reduce medial compartment joint loads by applying a corrective valgus moment.
The system incorporates three core technological sub-components:

- **Dynamic Biomechanical Hinge:** An adjustable, dual-axis polycentric mechanical joint that replicates the anatomical rolling and gliding kinematics of the natural human knee.
- **Tension-Force Matrix (TFM):** A proprietary network of adjustable elastomeric tension straps that allow clinicians or patients to calibrate a targeted offloading force (ranging from 5 N to 25 N) depending on the severity of joint degradation.
- **Thermoformed Hypoallergenic Interface:** Breathable, medical-grade compression sleeves engineered to minimize shear stress on cutaneous tissue, mitigate device migration, and distribute localized corrective pressure evenly across the femoral and tibial anchors.

2. Clinical Data Evaluation Strategy & Methodology

The clinical evidence base establishing the conformity, performance, and safety of the ABC Knee Assist Orthotic System consists of a systematic evaluation of data derived from three distinct clinical trial streams, encompassing a pooled cohort of N = 345 patients.

2.1 Clinical Evidence Matrix

The clinical dataset consists of the three foundational protocols outlined below:

Study Identifier & Design	Patient Cohort (N)	Evaluation Timeline	Primary Objective
Study ABC-01: Prospective, Multicenter, Observational	n = 150	12 Weeks	Assess real-world patient compliance, daily wear-time durability, and longitudinal pain relief profiles.
Study ABC-02: Prospective, Single-Center, Observational	n = 75	24 Weeks	Quantify improvements in objective biomechanical gait parameters and long-term functional mobility.
Study ABC-RCT-03: Randomized, Controlled, Multi-center Feasibility	n = 120 *(1:1 allocation vs. standard elastic compression sleeve)*	12 Weeks	Demonstrate superiority in pain mitigation and physical function scores against a baseline control.

3. Clinical Performance & Efficacy Outcomes

Across the evaluated clinical trials, the ABC Knee Assist Orthotic System demonstrated statistically significant, clinically meaningful improvements across all primary and secondary functional endpoints.

3.1 Pain Reduction (Visual Analog Scale - VAS)

In the randomized feasibility study (**Study ABC-RCT-03**), the active device cohort experienced an immediate and sustained reduction in weight-bearing pain.

- **Baseline Scores:** The average baseline VAS score was 6.8 ±1.2 cm on a 10 cm scale.
- **Week 12 Outcomes:** The ABC Knee Assist arm dropped to a mean VAS score of 3.2 ± 0.9 cm ($p < 0.001$), representing a 53% decrease in subjective pain perception.

- **Control Group Comparison:** The standard elastic sleeve control group showed a negligible decrease from a baseline of 6.7 cm to 5.9 cm at Week 12 ($p = 0.14$).

3.2 Objective Mobility (6-Minute Walk Test - 6MWT)

Functional endurance was objectively measured utilizing the standardized 6MWT across both prospective observational cohorts (**Study ABC-01** and **Study ABC-02**).

- **Distance Gains:** Pooled data demonstrated a statistically significant increase in total walking distance from a baseline average of 315 meters ± 42 m to 428 meters ± 38 m at the 12-week checkmark ($p < 0.01$).
- **Long-Term Maintenance:** In the 24-week longitudinal follow-up (**Study ABC-02**), the physical distance extension was maintained (432 meters), indicating no functional ceiling effect or degradation in device therapeutic performance.

3.3 Subjective Physical Function (WOMAC Sub-Scores)

The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) was deployed to track patient-reported physical outcomes.

- **WOMAC Stiffness Sub-scale:** Improved by a mean of 42% from baseline across all active cohorts by Week 12.
- **WOMAC Physical Function Sub-scale:** Demonstrated a statistically significant reduction in overall functional limitation ($p < 0.001$). Patients reported a pronounced decrease in joint hesitation during high-load tasks such as stair climbing, standing up from a seated position, and entering or exiting vehicles.

4. Safety & Tolerability Profile

The safety evaluation profile incorporates clinical trial adverse event tracking alongside a review of global Post-Market Surveillance (PMS) data spanning an estimated 12,500 active user-months.

4.1 Device-Related Adverse Events

No serious device-related adverse events (SADEs), such as deep vein thrombosis (DVT), joint subluxation, or structural mechanical component failures resulting in patient falls, were reported during clinical evaluation or post-market tracking.

Non-serious, transient adverse device reactions were minor and limited to localized cutaneous or mechanical accommodation issues:

1.9% No Adverse Events Reported (n = 317)	
91.9% No Adverse Events Reported (n = 317)	8.1% Total Non-Serious Minor Reactions (n = 28)
	Contact Dermatitis / Skin Erythema: 4.6% (n = 16) | (Resolved via strap tension readjustment and skin rest)
	Transient Soft-Tissue Discomfort: 3.5% (n = 12) (Resolved within the first 7 days of joint acclimatization)

5. Formal Benefit-Risk Assessment

5.1 Benefits Characterization

The clinical benefits derived from the use of the ABC Knee Assist Orthotic System are profound for a non-invasive intervention. The device successfully unloads the compromised knee compartment, achieving a documented, statistically significant reduction in chronic pain and a measurable enhancement in daily locomotive capacity. These functional improvements directly correlate with an upgraded Quality of Life (QoL) and may safely delay the clinical necessity for invasive surgical interventions like Total Knee Arthroplasty (TKA).

5.2 Risks Characterization

The risks identified with the use of the device are exclusively non-serious, low-severity, localized dermal or muscular discomforts. These cutaneous risks are predictable, completely reversible, and easily managed via routine patient education, initial compliance coaching, and proper strap calibration.

5.3 Benefit-Risk Balance Matrix

Given that the device is entirely non-invasive, does not alter internal joint anatomy, presents zero risk of systemic toxicity, and yields highly reproducible functional mobility outcomes, the clinical benefits of

the ABC Knee Assist Orthotic System heavily outweigh the minimal residual risks associated with its daily mechanical wear.

6. Regulatory Conclusion & Post-Market Mandate

The clinical evidence compiled across multiple independent studies establishes that the ABC Knee Assist Orthotic System achieves its stated performance specifications and operates safely when deployed in accordance with its labeled instructions for use. The clinical safety and performance profile is fully compliant with the Essential Principles of Safety and Performance.

To maintain this favorable clinical stance, the Sponsor mandates a comprehensive Post-Market Clinical Follow-up (PMCF) registry. This registry will actively track an unselected, real-world cohort of 500 patients over a 24-month horizon to continuously monitor long-term skin integrity, mechanical components degradation rates, and the sustainability of pain management efficacy.