PMCF Study need Assessment

Device Information	
Product Name	
Description of the Device (short; focus on technical specifications)	
Device class and classification rationale	
Intended purpose	
Contraindications	
Basic UDI-DI	
FDA code and/or other applicable codes (e.g. MDA/MDN codes)	

Novelty	
The design of the device, the materials, substances, principles of operation, technology, or medical indications are novel	
Justification	Applies

Equivalence	
CE marking was based on equivalence	
Response	Applies

Inherent Risks/ Intended Population	
▪ High risk with respect to the intended population and/or a subgroup (e.g. elderly, pediatrics, patients with as specific comorbidity etc.) ▪ Identification of previously unstudied subpopulations which may be impacting the different benefit/risk-ratio of the device ▪ Difficulty to generalize the clinical outcomes of available clinical investigations.	
Justification	Applies

Significant Design Changes	
There is a significant change to the device that has resulted or is expected to result in the revision of its original intended purpose.	
Justification	Applies

High Risk due to Anatomical Location	
The intended use is in a high-risk location, e.g. CNS	
Justification	Applies

High Risk due to Product Specifications	
There is a high product risk based on design, materials, components, invasiveness, or clinical procedures	
Justification	Applies

Unsubstantiated Indications	
The device's indications for use are not sufficiently supported with existing clinical evidence.	
Justification	Applies

Unsubstantiated Claims	
Clinical claims on clinical safety and performance are not sufficiently supported with existing clinical evidence.	
Justification	Applies

Long-term Safety and Performance	
▪ Emergence of new data (e.g. from vigilance databases) on safety and/or performance of the target device and/or similar devices. ▪ Consider any unaddressed CAPAs herein	
Justification	Applies

Risk Reduction	
Is there sufficient evidence to support the continued acceptability of the benefit-risk ratio of the device?	
Justification	Applies

Expected Intended Lifetime	
▪ Unanswered questions on the long-term safety and performance of the target device. ▪ Currently available clinical investigations do not cover the whole range of the intended lifetime of the target device.	
Justification	Applies

Insufficient/Incomplete previous Clinical Investigations	
There are unaddressed issues with respect to results of previous clinical investigation(s) including adverse events	
Justification	Applies

Risk profile of similar medical devices	
▪ Emergent risks identified in the literature for similar devices in the same intended medical field ▪ New information on safety or performance of the target device and/or similar emerges from the literature	
Justification	Applies

Health Economics/ Reimbursement /Market Access	
Clinical evidence is necessary to support market access and/or continued market acceptance.	
Justification	Applies