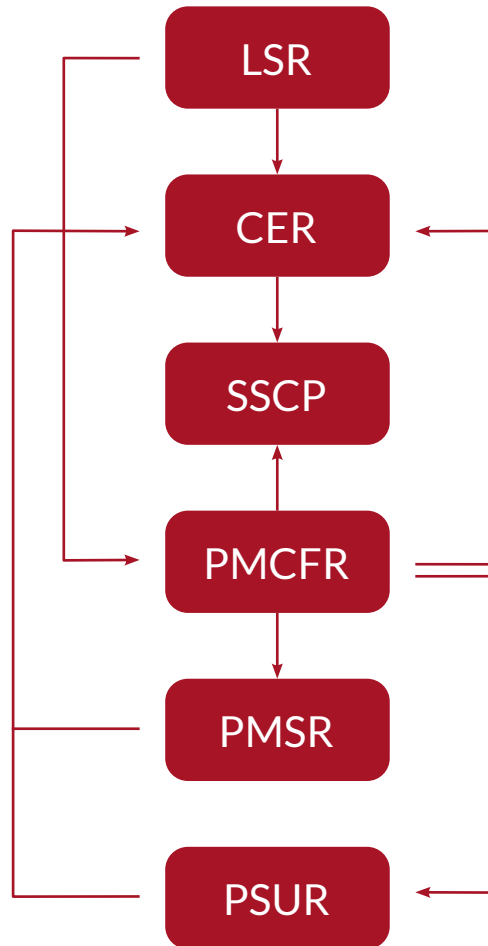


Report or summary



Corresponding process	Description of summary	Classes	Update frequency
Literature Search	Periodic searches in PubMed and Embase	All classes	When needed
Clinical Evaluation	Clinical data from literature, data held and generated by manufacturer including PMCF/PMS data	All classes	2-5 years IIa and IIb Annually for class III and implants IIa/IIb
Safety and Clinical Performance	Includes summary of CER and relevant information on PMCF among other things Written clearly to the intended user/patient	Class III and implants IIa/IIb	Annually
Post Market Clinical Follow up	Updates the clinical evaluation Clinically relevant information coming from post-market surveillance and literature	All classes	When needed or at least 2-5 years for class IIa and IIb At least annually for class III and implants IIa/IIb
Post Market Surveillance	Complaints, vigilance, trend reporting, FSCAs, registers Outcome assessed in CER	Class I	When necessary
Periodically Safety Update Report	Conclusion on benefit risk determination Main findings of PMCF Sales volume, usage frequency	All classes other than class I	At least annually for class IIb and class III devices/implants IIa/IIb At least every two years for class IIa

Alle Blog-Beiträge unter: www.qtec-group.com/news/

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