Format for Clinical evaluation

1.	**General Details**	
1.1	State the proprietary name of the device	
1.2	Any code names assigned during device development.	
1.3	Identify the manufacturer(s) of the device.	
2.	**Description of the device and its intended application**	**Location of Document**
2.1	Provide a concise physical description of the device	F1 Dscription of Device Technical Files Y1 Theory of device
2.2	Cross referencing to relevant sections of the manufacturer's technical information as appropriate	
2.3	The description should cover information such as:	
2.4	materials	T 1 Specifications of Materials : T 2 Material Safety Data Sheet
2.5	whether it incorporates a medicinal substance	N/A
2.6	(already on the market or new	Y 1 Theory of device L 1 promotional literature E 5.3 Competitor instructions for use
2.7	tissues	N/A
2.8	blood products;	N/A
2.9	The device components, including software and accessories;	R 1 Component breakdown T 1 Specifications of materials F 4 Description of Accessories J 11 Photographs of sub assemblies (if they exist)
2.10	mechanical characteristics;	
2.11	others, such as sterile vs. non-sterile,	
2.12	radioactivity etc.	N/A
2.13	State the intended application of the device	F 5 Instructions for use
2.14	Single use	
2.15	Re-useable	
2.16	invasive/non invasive	
2.17	implantable;duration of use or contact with the body; organs, tissues or body fluids contacted by the device.	N/A
2.18	Describe how the device achieves its intended purpose.	F 1 Description of device Y 1 Theory of device
3	**3. Intended therapeutic and/or diagnostic indications and claims**	L 1 Promotional literature
3.1	State the medical conditions to be treated. including target treatment group and diseases.	
3.2	Outline any specific safety or performance claims made for the device	L 1 Promotional material
4	**4. Context of the evaluation and choice of clinical data types**	
4.1	Outline the developmental context for the device. The information should include whether the device is based on a new technology, . The amount of information will differ according to the history of the technology. Where a completely new technology has been developed, this section would need to give an overview of the developmental process and the points in the development cycle at which clinical data have been generated. For long standing technology, a shorter description of the history of the technology (with appropriate references) could be used. Clearly state if the clinical data used in the evaluation are for an equivalent device.	
4.2	a new clinical application of an existing technology,	
4.3	or the result of incremental change of an existing technology	
4.4	Identify the equivalent device(s) and provide a justification of the equivalency, cross-referenced to the relevant non-clinical documentation that supports the claim.	E 5.3 Competitive literature and papers
4.5	State the Essential Requirements relevant to the device in question, in particular, any special	C 1 Essential requirements
4.6	design features that pose special performance or safety concerns (e.g. presence of medicinal ,human or	

	animal components) that were identified in the device risk management documentation and that required assessment from a clinical perspective.	
4.7	Outline how these considerations were used to choose the types of clinical data used for the evaluation. Where published scientific literature has been used, provide a brief outline of the searching/retrieval process, cross-referenced to the literature search protocol and reports.	
5	**5. Summary of the clinical data and appraisal**	
5.1	Provide a tabulation of the clinical data used in the evaluation, categorised according to whether the data address the performance or the safety of the device in question. (Note: many individual data sets will address both safety and performance.) Within each category, order the data according to the importance of their contribution to establishing the safety and performance of the device and in relation to any specific claims about performance or safety.	
5.2	Additionally, provide a brief outline of the data appraisal methods used in the evaluation, including any weighting criteria, and a summary of the key results.	Google
5.3	Include full citations for literature-based data and the titles and investigation codes (if relevant) of any clinical investigation reports.	
5.4	Cross-reference the entry for each piece of data to its location in the manufacturer's technical documentation.	E 5.3 Competition instructions L 1 Literature reviews
	6. Data analysis	
6.1	**Performance**	
6.1.1	**Provide a description of the analysis used to assess performance.**	
6.1.2	Identify the datasets that are considered to be the most important in contributing to the demonstration of the overall performance of the device and, where useful, particular performance characteristics.	
6.1.3	Outline why they are considered to be "pivotal" and how they demonstrate the performance of the device collectively (e.g. consistency of results, statistical significance, clinically significance of effects).	
6.2	**Safety**	
6.2.1	Describe the total experience with the device, including numbers and characteristics of patients exposed to the device; and duration of follow-up of device recipients.	Approximate sales
6.2.2	Provide a summary of device-related adverse events, paying particular attention to serious adverse events.	H 2 User Feedback H 3 Analysis of complaints
6.2.3	Provide specific comment on whether the safety characteristics and intended purpose of the device requires training of the end-user.	F 9 Training information
6.3	**Product Literature and Instructions for Use**	
	State whether the manufacturer's proposed product literature and Instructions for Use are consistent with the clinical data and cover all the hazards and other clinically relevant information that may impact on the use of the device.	L 1 Promotional literature F 5 Instructions for use
	7. Conclusions	
7.1	Outline clearly the conclusions reached about the safety	
7.2	and performance of the device from the evaluation, with respect to the intended use of the device.	
7.3	State whether the risks identified in the risk management documentation have been addressed by the clinical data.	
7.4	For each proposed clinical indication state whether:	
7.5	the clinical evidence demonstrates conformity with relevant Essential Requirements;	C 1 Essential requirements
7.6	the performance and safety of the device as claimed have been established; and	Yes safety record
7.7	the risks associated with the use of the device are acceptable when weighed against the benefits to the patient	E 3 Risk Analysis report