1 General details

State the proprietary name of the device and any code names assigned during device development.

Identify the manufacturer(s) of the device.

2 Description of the device and its intended application

Provide a concise physical description of the device, cross referencing to relevant sections of the manufacturer's technical information as appropriate. The description should cover information such as:

- materials, including whether it incorporates a medicinal substance (already on the market or new), tissues, or blood products;
- the device components, including software and accessories;
- mechanical characteristics; and
- others, such as sterile vs. non-sterile, radioactivity etc.

State the intended application of the device – single use/reusable; invasive/non invasive; implantable; duration of use or contact with the body; organs, tissues or body fluids contacted by the device.

Describe how the device achieves its intended purpose.

3 Intended therapeutic and/or diagnostic indications and claims

State the medical conditions to be treated, including target treatment group and diseases.

Outline any specific safety or performance claims made for the device

4 Context of the evaluation and choice of clinical data types

Outline the developmental context for the device. The information should include whether the device is based on a new technology, a new clinical application of an existing technology, or the result of incremental change of an existing 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 a comparable

device. Identify the comparable device(s) and provide a justification of the comparability, cross-referenced to the relevant non-clinical documentation that supports the claim.

State the Essential Principles relevant to the device in question, in particular, any special 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.

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 Summary of the clinical data and appraisal

Provide a tabulation of the clinical data used in the evaluation, categorized 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. 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.

Include full citations for literature-based data and the titles and investigation codes (if relevant) of any clinical investigation reports.

Cross-reference the entry for each piece of data to its location in the manufacturer's technical documentation.

6 Data analysis

6.1 **Performance**

Provide a description of the analysis used to assess performance.

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. 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

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.

Provide a summary of device-related adverse events, paying particular attention to serious adverse events.

Provide specific comment on whether the safety characteristics and intended purpose of the device requires training of the end-user.

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.

7 Conclusions

Outline clearly the conclusions reached about the safety and performance of the device from the evaluation, with respect to the intended use of the device. State whether the risks identified in the risk management documentation have been addressed by the clinical data.

For each proposed clinical indication state whether:

- the clinical evidence demonstrates conformity with relevant Essential Principles;
- the performance and safety of the device as claimed have been established; and
- the risks associated with the use of the device are acceptable when weighed against the benefits to the patient