Ref No	Rev No.	Issue Date

PMCF Plan

1-The manufacturer's contact details:

.....

2-A description and specification of the medical device being studied:

.....

3-The activities related to the PCMF (these are both the general and specific methods and procedures you're using):

.....

4-References to any relevant parts of the technical documentation:

.....

5-An evaluation of clinical data for equivalent or similar devices:

.....

6-References to any applicable common specifications, harmonized standards, or guidance documents:

.....

7-Estimated date of the PMCF evaluation report:

.....

8-Responsibilities:

Role	Responsibility

9-Signature:

***Note:** The report will take the same basic structure, but you'll include the results of the activities you undertook and the impact of those results on your technical documentation. At the end of the report, you'll document your conclusion and how they relate to your PMCF plan.

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