**Post-market clinical follow-up control Procedure**

**Product Name:** ***{填写申报产品名称 }***

**Model:*{填写申报产品的具体型号}***

**Document No.: *{填写本文档编号}***

**Edition: *{填写本文档版本号}***

Drafted by: Date: ***{填写本文档编写日期}***

Checked by: Date: ***{填写本文档审核日期}***

Approved by: Date: ***{填写本文档批准日期}***

***{填写申请者的企业名称}（参考示例：Shenzhen Hlongmed Biotech Co.,Ltd.）***

*{此处放入PMCF的控制程序文档}*

*（参考示例：*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| *Modification Page*   |  |  |  |  |  | | --- | --- | --- | --- | --- | | *File No.* | *Amending Clause* | *Modification* | *Modifier/Modification Date* | *Effective Date* | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  | | | | | | | | | |
| *Prepared* | *Reviewed* | *Distribution Department sign* | | | | | | *Approved* |
| *Sales Department* | *R&D Department* | *Purchasing Department* | *Manufacturing Department* | *Quality Department* | *Administration Department* |
|  |  |  |  |  |  |  |  |  |
| 1. ***Purpose***   *to provide guidance on the appropriate use and conduct of PMCF studies to address issues linked to residual risks. The intention is not to impose new regulatory requirements.*   1. ***Scope***   *This procedure is applicable to the post marketing clinical follow-up process of all CE marked products that produce by our company.*   1. ***Duties***    1. ***manufacturers***   *proactively collect and evaluate clinical data from the use in or on humans of a device, confirming the safety and performance throughout the expected lifetime of the device, of ensuring the continued acceptability of identified risks*   1. ***Definitions***    1. ***clinical data***   *means information concerning safety or performance that is generated from the use of a device and is*  *sourced from the following:*  *— clinical investigation(s) of the device concerned,*  *— clinical investigation(s) or other studies reported in scientific literature, of a device for which equivalence to the device in question can be demonstrated,*  *— reports published in peer reviewed scientific literature on other clinical experience of either the device in question or a device for which equivalence to the device in question can be demonstrated,*  *— clinically relevant information coming from post-market surveillance, in particular the post-market clinical follow-up;*   * 1. ***clinical evaluation***   *means a systematic and planned process to continuously generate, collect, analyse and assess the clinical data pertaining to a device in order to verify the safety and performance, including clinical benefits, of the device when used as intended by the manufacturer;.*   * 1. ***clinical evidence***   *means clinical data and clinical evaluation results pertaining to a device of a sufficient amount and quality to allow a qualified assessment of whether the device is safe and achieves the intended clinical benefit(s), when used as intended by the manufacturer;.*   * 1. ***Post-market clinical follow-up (PMCF) study***   *A study carried out following the CE marking of a device and intended to answer specific questions relating to clinical safety or performance (i.e. residual risks) of a device when used in accordance with its approved labeling.*   1. ***Working Procedure***   ***The PMCF plan shall include at least***   * *the general methods and procedures of the PMCF to be applied, such as gathering of clinical experience gained, feedback from users, screening of scientific literature and of other sources of clinical data;* * *the specific methods and procedures of PMCF to be applied, such as evaluation of suitable registers or PMCF studies;* * *a rationale for the appropriateness of the methods and procedures referred to in points (a) and (b);* * *a reference to the relevant parts of the clinical evaluation report referred to in Section 4 and to the risk management referred to in Section 3 of Annex I;* * *the specific objectives to be addressed by the PMCF;* * *an evaluation of the clinical data relating to equivalent or similar devices;* * *reference to any relevant CS, harmonised standards when used by the manufacturer, and relevant guidance on PMCF; and;* * *a detailed and adequately justified time schedule for PMCF activities (e.g. analysis of PMCF data and reporting) to be undertaken by the manufacturer.*   ***PMCF studies***   * 1. ***Circumstances that may justify PMCF studies include, for example:：***   *- innovation, e.g., where the design of the device, the materials, substances, the principles of operation, the technology or the medical indications are novel;*  *- significant changes to the products or to its intended use for which premarket clinical evaluation and re-certification has been completed;*  *- high product related risk e.g. based on design, materials, components, invasiveness, clinical procedures;*  *- high risk anatomical locations;*  *- high risk target populations e.g. paediatrics, elderly;*  *- severity of disease/treatment challenges;*  *- questions of ability to generalise clinical investigation results;*  *- unanswered questions of long-term safety and performance;*  *- results from any previous clinical investigation, including adverse events or from post-market surveillance activities;*  *- identification of previously unstudied subpopulations which may show different enefit/risk-ratio e.g. hip implants in different ethnic populations*  *- continued validation in cases of discrepancy between reasonable premarket follow-up time scales and the expected life of the product;*  *- risks identified from the literature or other data sources for similar marketed devices*  *- interaction with other medical products or treatments;*  *- verification of safety and performance of device when exposed to a larger and more varied population of clinical users;*  *- emergence of new information on safety or performance;*  *- where CE marking was based on equivalence.*   * 1. *Following a proper premarket clinical evaluation, the decision to conduct PMCF studies must be based on the identification of possible residual risks and/or unclarity on long term clinical performance that may impact the benefit/risk ratio.*   2. *PMCF studies may review issues such as long-term performance and/or safety, the  occurrence of clinical events (e.g. delayed hypersensitivity reactions, thrombosis),  events specific to defined patient populations, or the performance and/or safety of the  device in a more representative population of users and patients*   3. *PMCF studies may not be required when the medium/long-term safety and clinical performance are already known from previous use of the device or where other appropriate post-market surveillance activities would provide sufficient data to address the risks.*   4. *Post-market clinical follow-up studies are performed on a device within its intended use/purpose(s) according to the instructions for use. It is important to note that PMCF studies must be conducted according to applicable laws and regulations and should involve an appropriate methodology and follow appropriate guidance and standards.*   5. *PMCF studies must be outlined as a well designed clinical investigation plan or study plan, and, as appropriate, include:*   *- clearly stated research question(s), objective(s) and related endpoints;*  *- scientifically sound design with an appropriate rationale and statistical analysis plan;*  *- a plan for conduct according to the appropriate standard(s);*  *- a plan for an analysis of the data and for drawing appropriate conclusion(s).*   * 1. ***Objectives of PMCF studies***   *The objective(s) of the study should be stated clearly and should address the residual risk(s) identified and be formulated to address one or more specific questions relating to the clinical safety or clinical performance of the device. A formal hypothesis should be clearly expressed*   * 1. ***Design of PMCF studies***   *PMCF studies should be designed to address the objective(s) of the study. The design may vary based on the objective(s), study hypothesis research question and endpoints and should be scientifically sound to allow for valid conclusions to be drawn.*   * 1. ***PMCF studies can follow several methodologies,***   *for example:*  *- the extended follow-up of patients enrolled in premarket investigations;*  *- a new clinical investigation;*  *- a review of data derived from a device registry; or*  *- a review of relevant retrospective data from patients previously exposed to the device.*   * 1. ***clinical investigation plan/study plan*** * *the study population (corresponding to the CE-mark scope);* * *inclusion/exclusion criteria;* * *rational and justification of the chosen study design including use of controls/control groups (where relevant; randomised or not);* * *the selection of sites and investigators;* * *study objectives and related study endpoints and statistical considerations;* * *the number of subjects involved;* * *the duration of patient follow-up;* * *the data to be collected;* * *the analysis plan including any interim reporting where appropriate to ensure continuous risk management based on clinical data; and* * *procedures/criteria for early study termination;* * *ethical considerations;* * *methods of quality control of data where appropriate.*   1. ***Implementation of the PMCF study, analysis of data and conclusion(s)***   *The study should:*   * *be executed with adequate control measures to assure compliance with the clinical investigation or study plan;* * *· include data analysis with conclusions drawn according to the analysis plan by someone with appropriate expertise; and*   1. ***The use of study data***   *The data and conclusions derived from the PMCF study are used to provide clinical evidence for the clinical evaluation process. This may result in the need to reassess whether the device continues to comply with the Essential Requirements. Such assessment may result in corrective or preventive actions, for example changes to the labelling/instructions for use, changes to manufacturing processes, changes to the device design, or public health notifications..*  ***PMCF Report***  *The manufacturer shall analyse the findings of the PMCF and document the results in a PMCF evaluation report that shall be part of the clinical evaluation report and the technical documentation.*  ***PMCF documents update***  *when receives below information, should be evaluate whether the PMCF plan and report needs to be updated:*   * *based on the results of its assessment of the PMS report and risk management report.* * *the obligations of the manufacturer changed* * *design changes or changes to manufacturing procedures* * *regulations and standards of product related had updated* * *customer complaints* * *don’t meet product specifications of performance, safety, labeling, regulations and other issues* * *adverse event*   *if there is no such information is received, then update the PMCF plan and report at least annually.*   1. ***Related documents***   *《Corrective and Preventive Measures Control Procedures》*  *《Advisory Notice Control Procedures》*  *《Vigilance System Control Procedures》）*   1. ***Related records***   *7.1《Field Safety Corrective Action Report》*  *7.2《POST-MARKET CLINICAL FOLLOW-UP Plan》*  *7.3《POST-MARKET CLINICAL FOLLOW-UP Report》）* | | | | | | | | |

*}*