**Appendix 1.12 Market analysis**

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*The device under evaluation is not put into the market. So there is no information from the market for market analysis. We only can collect information from equivalent device and similar device for market analysis. All information are analyzed and the risk are controlled and acceptable.*

*The summary is as follow:*

*For the device under evaluation, the device is not put into the market, so we do not collect any information.*

*For the equivalent device and similar device, the clinical evaluation report searches the experiences data from other user experience, and in the market, summarize blew:*

*The Database search Summary form of Clinical data about experience data is following:*

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| ***Source*** | ***Sources of data*** | | ***Search query*** | ***Search time frame*** | ***Search date*** | ***Number of search results*** | ***experience data of actual device*** | ***experience data of equivalent device*** |
| *adverse event and recall report databases* | *NMPA website* | | *\*\*\** | *\*\*\** | *\*\*\** | *\*\*\** | *\*\*\** | *\*\*\** |
| *\*\*\** | *\*\*\** | *\*\*\** | *\*\*\** |
| *\*\*\** | *\*\*\** | *\*\*\** | *\*\*\** |
| *\*\*\** | *\*\*\** | *\*\*\** | *\*\*\** |
| *\*\*\** | *\*\*\** | *\*\*\** | *\*\*\** |
| *\*\*\** | *\*\*\** | *\*\*\** | *\*\*\** |
| *\*\*\** | *\*\*\** | *\*\*\** | *\*\*\** |
| *\*\*\** | *\*\*\** | *\*\*\** | *\*\*\** |
| *FDA website* | *MAUDE* | *\*\*\** | *\*\*\** | *\*\*\** | *\*\*\** | *\*\*\** | *\*\*\** |
| *\*\*\** | *\*\*\** | *\*\*\** | *\*\*\** |
| *\*\*\** | *\*\*\** | *\*\*\** | *\*\*\** |
| *\*\*\** | *\*\*\** | *\*\*\** | *\*\*\** |
| *\*\*\** | *\*\*\** | *\*\*\** | *\*\*\** |
| *\*\*\** | *\*\*\** | *\*\*\** | *\*\*\** |
| *\*\*\** | *\*\*\** | *\*\*\** | *\*\*\** |
| *\*\*\** | *\*\*\** | *\*\*\** | *\*\*\** |
| *\*\*\** | *\*\*\** | *\*\*\** | *\*\*\** |
| *Medical Device Recalls* | *\*\*\** | *\*\*\** | *\*\*\** | *\*\*\** | *\*\*\** | *\*\*\** |
| *\*\*\** | *\*\*\** | *\*\*\** | *\*\*\** |
| *\*\*\** | *\*\*\** | *\*\*\** | *\*\*\** |
| *GOV.UK* | | *\*\*\** | *\*\*\** | *\*\*\** | *\*\*\** | *\*\*\** | *\*\*\** |
| *\*\*\** | *\*\*\** | *\*\*\** | *\*\*\** |
| *\*\*\** | *\*\*\** | *\*\*\** | *\*\*\** |
| *\*\*\** | *\*\*\** | *\*\*\** | *\*\*\** |
| *\*\*\** | *\*\*\** | *\*\*\** | *\*\*\** |
| *\*\*\** | *\*\*\** | *\*\*\** | *\*\*\** |

*There are some adverse events and recalls. While many adverse events and recalls are not applied to actual device, we omit these kinds of adverse events and recalls. Meanwhile, some adverse event and recalls repeat or describe the same things, we omit regards these adverse events or recalls as one representative to analyze the risk. So the summary of the data analysis indicate the kinds of adverse events and recalls, not all the adverse events and recalls.*

*The data, risk analysis and traceability table of experience data is following:*

*Experience data of device problem searched from NMPA website, UK gov. FDA MAUDE:*

|  |  |  |  |
| --- | --- | --- | --- |
| ***No*** | ***Device Problems*** | ***Is our product has similar risk? (Y/N)*** | ***Hazards No in RM report***  ***Or the justification for NA*** |
| *1* | *\*\** | *Y* | *\*\*\** |
| *2* | *\*\** | *Y* | *\*\*\** |
| *3* | *\*\** | *Y* | *\*\*\** |
| *4* | *\*\** | *Y* | *\*\*\** |
| *5* | *\*\** | *Y* | *\*\*\** |
| *6* | *\*\** | *Y* | *\*\*\** |

*Experience data of recall searched from NMPA website, UK gov. FDA MAUDE:*

|  |  |  |  |
| --- | --- | --- | --- |
| ***No*** | ***Recall reason*** | ***Is our product has similar risk? (Y/N)*** | ***Hazards No in RM report***  ***Or the justification for NA*** |
| *1* | *\*\** | *Y* | *\*\*\** |
| *2* | *\*\** | *Y* | *\*\*\** |
| *3* | *\*\** | *Y* | *\*\*\** |
| *4* | *\*\** | *Y* | *\*\*\** |

*The detailed of the above summarized contents can be refer to Annex 2 Literature search protocol and report and risk management report.*

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*【此处内容，可以与临床经验的搜索及搜索结果相互关联】*