**Marketing History Template**

**April 21, 2018**

1. **CANADA**

*Note 1: Marketing history of a Health Canada licensed, previous generation or previous version device can be used to support the safety and effectiveness of the subject device when the subject device has a short marketing history (i.e. ≤ 5 years) and/ or the sales numbers are not significant for the type of device.*

*Note 2: If a licensed previous generation/ version device is used to support safety and effectiveness of the subject device, the similarities and differences between the two devices should be provided using either a narrative or a table format.*

**Table 1: Canadian regulatory history**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Device Name** | **Licence Number** | **Month and Year first sold in Canada** | **Device Identifier**  (e.g.catalogue or model #) | **Authorization** | | | |
|  | **YES** | **NO** | **Total Quantities Authorized for Sale** |
| **Subject Device** |  |  |  | *List if different part numbers are available- do not list individually )* | **SAP** |  |  |  |
| **ITA** |  |  |  |
| **Licensed previous generation/ version device\*** |  |  |  |  | **SAP** |  |  |  |
| **ITA** |  |  |  |

*\* See Note 1 and 2.*

**Table 2: Units sold in Canada for reporting period MM/YY-MM/YY**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Device Name** | **MM/YY-MM/YY** | ..add columns as desired/ needed | **Total Number of Units Sold** |
| **Subject Device** |  |  |  |  |
| **Licensed previous generation/ version device\*** |  |  |  |  |

*\* See Note 1 and 2.*

1. **INTERNATIONAL**

*Note 3: If the subject device or the licensed previous generation/ version device is different from the international version (e.g. variations in design, labelling, specifications), the differences should be described using either a narrative or a table format.*

**Table 3: International regulatory history**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Device Name** | **Identifier(s) for Devices**  (e.g.catalogue or model #) | **Regulator\*\*** | **Approval Number** | **First Approval Date**  (month and year) | **Subject or Licensed previous generation/version device and international version are identical\*\*\***  (Yes/No) |
| **Subject Device** |  | *List if different part numbers are available – do not list individually).* |  |  |  |  |
| **Licensed previous generation/ version device\*** |  |  |  |  |  |  |

*\* See Note 1 and 2.*

***\*\**** *e.g. Australia – TGA; European Union (CE mark); Japan; United States – FDA; WHO, Country 1; Country 2 etc.*

*\*\*\* See Note 3.*

**Table 4: Units sold internationally for reporting period MM/YY-MM/YY**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Device Name** | **Country** | **MM/YY-MM/YY** | add columns as desired/ needed | **Total Number of Units Sold** |
| **Subject Device** |  |  |  |  |  |
|  |  |  |  |  |
|  | **Total** |  |  |  |
| **Licensed previous generation/ version device\*** |  |  |  |  |  |
|  |  |  |  |  |
|  | **Total** |  |  |  |

*\* See Note 1and 2.*

1. **COMPLAINTS/ INCIDENT REPORTS/ RECALLS/ FIELD SAFETY CORRECTIONS**

*Note 4: If marketing history is presented for a licensed previous generation/ version device, then the associated complaints/ incident reports/ recalls/ field safety corrections should be provided for that device.*

*Note 5: Complaints should be related to the performance characteristics or safety of the device.*

*Note 6:”Confirmed” means the manufacturer was able to confirm the reporting problem (e.g. received the device back, visited the facility site, etc.); “Not confirmed” means the user’s reported problem could not be confirmed by the manufacturer.*

**Table 5: Summary of complaints for reporting period MM/YY-MM/YY\***

|  |  |  |  |
| --- | --- | --- | --- |
| **Complaint type\*\*** | **Total Complaints** | | **Complaint Rate (%)** |
| **Confirmed\*\*\*** | **Not Confirmed\*\*\*** |
| e.g. false positive result |  |  |  |
| e.g. manufacturing |  |  |  |

*\* See Note 4.*

*\*\* See Note 5.*

*\*\*\* See Note 6.*

**Table 6: Incident reports, incident rates and summary of incidents for reporting period MM/YY to MM/YY\***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Country** | **Number of Units Sold** | **Number of Incidents Reported** | **Incident Rate (%)** | **Event type** | **Event description** |
|  |  |  | *Incident rate = # adverse events and incidents divided by # units sold per country x 100\*\*.* |  | *Summary of event, seriousness, investigation results, action taken or risk mitigation, outcome of issue.* |
| **Total** |  |  |  |  |  |

*\* See Note 4.*

*\*\* For multiple use devices this formula may not be appropriate; in some cases it may be more correct to report incident rate by the number of uses rather than the number of sales; in these cases, the formula use should be specified.*

**Table 7: Recalls and Field Safety Corrections for reporting period MM/YY to MM/YY\***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Recall/ FSCA** | **Report Number** | **Country** | **Description/**  **Rationale/**  **Overview of Action** | **Action to prevent recurrence** | **Outcome/ Status** |
|  |  |  |  |  |  |

*\* See Note 4.*