**Executive Summary Template – In Vitro Diagnostic Devices**

<Remove any sections/items not applicable to the submission>

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| --- | --- |
|  |  |
| **Name of the Device:** | <***Insert Text:*** Trade Name, Proprietary Name> |
| **Intended/Indications for Use:** | *<Insert Text>* |
| **Intended User:** | *<Insert Text>* |
| **Device Classification:** | Choose an item. |
| **Classification Rule:** | Choose an item. |
| **Legal Manufacturer:** | <***Insert Text:*** Name and address of the legal manufacturer as stated on the device label> |
| **Physical Manufacturing Location** | ***<Insert Text:***Name and address of the establishment where the device is being manufactured, if different from the legal manufacturer**>** |
| **Business Relationship** | ***<Insert text:*** If the trademark owner is not the legal manufacturer, add extra information about the relationship of the trademark owner and the legal manufacturer relationship**>** |
| **Canadian Importer:** | <***Insert Text***> |
| **Health Canada Correspondence:** | <***Insert Text:*** Summary of pre-submission discussions with Health Canada worth noting> |
| **For significant amendments:** | <***Insert Text:*** Include the licence name and number you are amending, application number (if available). Provide a description of the change requested (e.g., changes in design, performance, indications, changes to manufacturing processes, manufacturing facilities, suppliers> |
| **Additional Notes:** | <***Insert Text:*** Any high-level background information or unusual details that the manufacturer wishes to highlight in relation to the device, its history or relation to other approved devices to provide context to the submission.> |

**Description of the Device:**

* Background/introduction
* Purpose of the submission
* Concise Description of the device, not just a cut and paste from the submission
* Consider adding items such as whether the device is used in conjunction with other devices/interdependent devices, compatibility, etc.)
* If cross-referring applicable data, specify the application number and why this data is not necessary.

**Predicates or Comparator Devices:**

* Name, manufacturer, licence number(s)
* Include a brief description of how your product relates to predicates or comparator devices licensed in Canada
* If a Canadian licensed device is not available, provide a rationale to justify the use of the comparator device or chosen gold standard method
* For amendment applications, add a clear and concise summary of what has changed and what remains the same from the currently licensed device, when possible use a Comparison Table.

**Summary of Performance Information:**

* If applicable, highlight any specific relevant salient issues.
* Provide the equivalent of an “Abstract” that concisely summarizes the analytical and clinical studies to support the performance claims of the device, or use the following table

|  |  |
| --- | --- |
| **Specification** | **Claim (as stated in the Directions for Use)** |
| Measuring Range |  |
| Precision |  |
| Method Comparison |  |
| Interference |  |
| Hook Effect |  |
| Limit of Quantitation (LoQ) |  |
| LoD/LoB |  |
| … |  |