**Cover Letter / Letters of Reference**

**1 Attach your Cover Letter**

【If this is a premarket notification, the cover letter should include your preference for continued confidentiality (21 CFR 807.95). For all premarket submissions, if the device was marketed under an EUA or enforcement policy guidance during the COVID-19 public health emergency, include the EUA number or guidance information.

The cover letter should state applicant or sponsor name and/or their authorized representative, the type of submission, the common name of the device (if applicable), device trade name or proprietary name (both of the base device and a new name if one is given to the new version/model of the device) and include the purpose of the application, including any changes being made to existing approvals.

If applicable and accepted by the regulator, it should include information pertaining to any Master Files referenced by the submission.

If applicable, acknowledgement that a device sample has been submitted or offered alternatives to allow the regulator to view or access the device (when the regulator requests a sample).

If the submission is requesting approval of a change that is the result of CAPA due to a recall, this should be stated.

If the submission is in response to a request for information from the regulator this should be stated and the date of that letter should be included as well as any reference number(s).

If the submission is unsolicited information, this should be stated and any related reference number(s) provided.

You should identify the regulatory jurisdication(s) in which marketing is sought.

Note: The cover letter should not contain any detailed scientific information.】

**2 Attach any Letters of Reference**

**【**This includes letters from the owner of any separate document referenced in the submission (e.g. Master File or previous marketing submission), granting access to the information in the referenced document.

FDA typically refers to a “Letter of Reference” as a “Letter of Authorization.” Information in a Master File (MAF) may be incorporated by reference in a client’s PMA, 510(k), or IDE, or other submissions to FDA. Their use of information in an MAF can only be authorized by the MAF holder or by a designated agent if so authorized. This authorization must be on company letterhead or that of the agent or representative. After FDA has referred to an MAF and the client’s application has been approved, authorization cannot be withdrawn.

An MAF holder should provide a letter of authorization directly to a client with instructions that: (1) the original of the authorization letter be included in the original copy of the client’s submission and (2) a copy be placed in each subsequent copy of the client’s submission. An authorization letter should not be sent directly to CDRH for inclusion in the MAF or the client’s submission.

The letters should specify the scope of access granted.**】**