**2. COVER MEMO**

**CompanyLeterhead[[1]](#footnote-1)**

*Date*

U.S. Food and Drug Administration

Center for Devices and Radiological Health

Document Control Center – WO66 G609

**Attention:**

10903 New Hampshire Avenue

Silver Spring, MD 20993-0002

**Reference: Pre-Submission-Written Feedback Request**

We are requesting a Pre-Submission (Pre-Sub) requesting FDA’s formal written feedback to specific questions in order to clarify the product development and follow-on application preparation of *Device Proprietary Name* codified at 21 CFR §XXX.XXXX, *Classification Name.*

*Device or Product Description*

*An explanation of how the device functions, the basic scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device.*

We have included specific questions regarding biocompatibility, non-clinical performance evaluation, animal *in vivo* testing and our regulatory approach for the proposed devices that we feel answers are required in order to properly address the health risks and mitigation measures of the special controls of 21 CFR §XXX.XXXX.

As part of the Medical Device User Fee Amendments of 2017 (MDUFA IV), industry and the Agency agreed to refine the Q-Sub Program with changes related to the scheduling of Pre-Sub meetings and a new performance goal on the timing of FDA feedback for Pre-Subs.[[2]](#footnote-2) Written feedback should be provided within 70 days of receipt of the accepted submission and will serve as the official record of the Agency’s feedback.

Enclosed with this signed cover letter is an eCopy of our Pre-Sub submission which is being provided on a CD-R disc as specified in the guidance document, “eCopy Program for Medical Device Submissions”, issued December 16, 2019.

**Administrative Information**

|  |  |
| --- | --- |
| **Company Name** |  |
| **Address** |  |
| **Contact Information** | NameTitlePhone: FAX : Email:   |
| **Proprietary Names** |  |
| **Device Common Name** |  |
| **Device Classification Name** |  |
| **Q-Sub Type** |  |

If you require further clarification or additional information, please contact me directly at (XXX) XXX-XXXX, or email: John Smith@XXXX.com

Thank you in advance for your timely consideration of this matter.

Sincerely,

**Company Name**

(may be a wet (i.e., ink) signature or a valid digital signature)

Typed Name

Title

*End of Cover Memo*

1. It is recommended that your company cover letter also be included as a PDF in your eCopy, but it is not required. [↑](#footnote-ref-1)
2. See 163 CONG. REC. S4729-S4736 (daily ed. August 2, 2017) (Food and Drug Administration User Fee Reauthorization), also available at https://www.fda.gov/media/102699/download [↑](#footnote-ref-2)