Month XY, 20XY

U.S. Food and Drug Administration

Center for Devices and Radiological Health

Document Control Center – WO66-G609

10903 New Hampshire Avenue

Silver Spring, MD 20993-0002

Attn: *Jane Doe*, MD

Director, Division of Something

**RE: Study Risk Determination: Written Response Requested**

Dear *Dr. Doe*:

Please find enclosed an electronic copy, on CD, of this Study Risk Determination request.

Per the FDA guidance *Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program*, I am submitting this study risk determination request to determine if an IDE is required for the attached protocol entitled, “A Phase I Trial of artificial XY implant in Humans”.

I request written feedback on whether FDA considers this study to be significant risk, non-significant risk, or exempt from the IDE regulations.

If there are any questions regarding this submission, please contact myself or Jacob Durham, at (919) 668-xxxx or jdurham@notes.duke.edu. Mr. Durham is authorized to communicate with the FDA on any issue relating to this study risk determination request.

Sincerely,

John Doe, MD

Professor, Department of Something

Duke University

Phone: 919-684-XXXX

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