Q SUBMISSION: STUDY RISK DETERMINATION REQUEST

Title of Proposed Trial

Name of Sponsor Investigator, MD

X Professor, Department

DUKE UNIVERSITY

Date of Submission

# FDA Form 3514

*Link to the form:* [*http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM080872.pdf*](http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM080872.pdf)

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# Purpose

The goal of this Study Risk Determination request is to receive an FDA determination for whether the planned medical device clinical study is significant risk, non-significant risk, or exempt from IDE regulations as defined by 21 CFR part 812*.*

# Regulatory History

*List any relevant previous communications with FDA about the subject device including but not limited to any marketing submission, IDE, 513(g), and/or Q-Sub application numbers relevant to the Study Risk Determination. Include a brief summary of these previous FDA interactions and submissions (and submission number(s)), including feedback received and resolution of that feedback (or justification of alternative paths) as applicable.*

# Device Description

*Please provide sufficient information regarding the device description, which may include:*

* *explanation of how the device functions*
* *pictures of the device (where applicable);*
* *engineering drawings (where applicable);*
* *physical, chemical and/or biological processes/principles used by the device to generate device output, if applicable*
* *significant physical, performance, and biological characteristics of the device , if applicable;*
* *samples to demonstrate the use of the device (where feasible and appropriate);*
* *explanation of the user interface and/or how the device interacts with other devices or with the user (medical professional and/or patient);*
* *explanation of the materials used in the device;*
* *brief description of the manufacturing process should be included if the manufacturing process may affect safety and/or effectiveness, and may therefore impact FDA’s recommendations regarding device testing; discussion of the mechanism of action and how the device and/or, if applicable, device output is used;*
* *basic scientific concepts that form the basis for the device; and*
* *the generic name of the device as well as any proprietary name or trade name, if applicable*

*Make sure your device description is clear and describes ALL elements of your proposed device, in addition to providing its dimensions and all of the dimensions of its components. Diagrams of both your device and an exploded view of your device with all of the components identified are very helpful.*

*Clearly identify how all components of your device fit together and are held together. Note that while the FDA does not ask for specific manufacturing information on how your device is assembled, it is still very useful for them to know if two components are glued together end to end, if one component can fit inside the other and is glued, etc.*

*Clearly describe the functional purpose of each element of your device. This helps FDA both understand the components of your device and your device as a whole.*

*Clearly identify all of the different sizes and configurations your device comes in. It is often helpful if this is done in a tabular format.*

*Always make sure you use consistent terminology for each component of your device in your submission.*

*In addition to pictures and a written description, other information about the clinical use of the device, such as a surgical technique guide or video of how the device is used in the clinical setting, may be helpful.*

# Proposed Intended Use/Indications for Use

*Please provide sufficient information regarding the proposed intended use/indications for use, which may include:*

* *description of the disease or condition the device will prevent, mitigate, screen, monitor, treat, or diagnose;*
* *identification of the patient population for which the device is intended;*
* *part of the body or type of tissue to which the device will be applied or interacting;*
* *frequency of use;*
* *physiological use; and*
* *statement of whether the device is intended for prescription and/or over-the-counter use.*

# Protocol

*Please insert the study protocol.*

* *Rather than inserting the protocol within this document, we recommend that you assemble the Q-Submission after separately printing to PDF this Study Risk Determination request and the protocol.*