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)

# Table of Contents

[1. FDA Form 3514 3](#_Toc388276460)

[2. Table of Contents 9](#_Toc388276461)

[3. Device Description 10](#_Toc388276462)

[4. Description of Device Use 10](#_Toc388276463)

[5. Description of the Population 10](#_Toc388276464)

[6. Protocol 10](#_Toc388276465)

# Device Description

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

* *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;*
* *physical and biological characteristics of the device output, 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).*

# Description of Device Use

*Please provide sufficient information regarding how the device will be used in the study, if not already included in the protocol. A description of device use may include:*

* *the proposed intended use/indications for use;*
* *identification of the disease or condition the device is indicated to prevent, mitigate, screen, monitor, treat, or diagnose;*
* *part of the body or type of tissue to which the device will be applied or interacting;*
* *frequency of use; and/or*
* *physiological use.*

# Description of the Population

*Please provide sufficient information regarding the study population, if not already included in the protocol. A description of the population may include:*

* *age (e.g., adult, pediatric, specific age limitations);*
* *patient type (e.g., asymptomatic, symptomatic, already diagnosed);*
* *whether patients will be recipients of combination treatments;*
* *general description of inclusion/exclusion criteria; and/or*
* *how the clinical study population reflects the intended use population.*

# 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.*

***Important Notes:***

*You must submit the request as an eCopy (section 745(A)(b) of the FD&C Act). For information about how to comply with the eCopy program, please see FDA guidance “eCopy Program for Medical Device Submissions” (*[*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/ecopy-program-medical-device-submissions*](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/ecopy-program-medical-device-submissions)*).*

*For products regulated by the Center for Devices and Radiologic Health (CDRH), submissions should be sent to:*

*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*