**INVESTIGATIONAL DEVICE EXEMPTION**

**ORIGINAL APPLICATION**

Study Title

Name of Study Sponsor Investigator, MD

Alternative Contact

Date of Submission

# FDA Form 3514

*The use of this form is optional. If you choose not to use the form, ensure that the relevant information is contained in the cover letter:*

* *Statement that this is an original IDE submission*
* *Device name and intended use*
* *Sponsor’s contact information*
  + *Name, address, telephone number, fax number, email address*
* *Manufacturer information* 
  + *Name, address, contact person, telephone number, fax*

*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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# Name and Address of the Sponsor

Name of Study Sponsor Investigator, MD

Alternative Contact

# Report of Prior Investigations

# Investigational Plan

**3.1 Purpose**

## Protocol

*A written protocol describing the methodology to be used and an analysis of the protocol demonstrating that the investigation is scientifically sound.*

*Rather than insert the protocol within this document, we recommend that you assemble the IDE after separately printing this IDE document and the protocol. To ensure that the TOC on Page 2 reflects the true number of pages in the IDE, format the page number on the Informed Consent page to reflect the additional pages in the protocol.*

*To format the page number, highlight the page number in the footer, right click and choose “Format Page Numbers”. Then click “Start numbering at” and put the new number accounting for the number of inserted pages. Also note, to be able reformate page numbers, you need to insert a “section break (next page)” rather than a simple page break.*

## Risk Analysis

## Description of Device

## Monitoring Procedures

# Manufacturing Information

# Example of the Investigators Agreement

All investigators have signed the Investigator’s Agreement. A list of the names and addresses of all the investigators who have signed the agreement is as follows.

The template for the signed investigator’s agreement is:

INVESTIGATOR AGREEMENT

# Investigator Certification

As required for an IDE study, we commit to obtain a signed investigator agreement from all current investigators who are participating in the investigation. Additionally, no future investigators will be added until they have signed the agreement.

# IRB Information

The name, address, and chairperson of the IRB that will be providing regulatory oversight is as follows.

Debbie Dykhuis

Executive Director

Phone: (612) 626-4851

Email: dykhu001@umn.edu

Institutional Research Board

Email: [irb@umn.edu](mailto:irb@umn.edu)  
Phone: (612) 626-5654

Office Location:  
D528 Mayo Memorial Building

Mailing Address  
MMC 820  
420 Delaware St. SE  
Minneapolis, MN 55455-0392

# Name and Address of Other Investigational Institutions

# Sale of the Device

The device will be used in standard care processes in this study. Accordingly, the sponsor does not believe this study constitutes commercialization of the investigational device for this indication.

# Environmental Assessment

*A claim for categorical exclusion under § 25.30 or § 25.34 or environmental assessment under § 25.40.*

*Please maintain this header and include the following statement*: Please note that an environmental assessment as required under 21 CFR 25.40 or a claim for categorical exclusion under 21 CFR 25.30 or 25.34 is no longer required [§25.34(g)].

# Labeling

# Consent Materials

# Additional Information

*Any other relevant information FDA requests for review of the application*, *including information previously submitted*.