

Investigational Device Study Supplemental Submission Form

I. STUDY INFORMATION	
Sponsor:	
Protocol Number:	
Device Name:	
CRO: (if applicable)	

II. DEVICE INFORMATION
<p>1. Has the FDA approved this device for marketing in the U.S.? <input type="checkbox"/> Yes* <input type="checkbox"/> No</p> <p style="margin-left: 20px;">*If Yes, describe the approved indication(s) of the device:</p> <p style="margin-left: 20px;">*If Yes, will the device for this study be used in accordance with its approved indication? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<p>2. Will this study involve an investigational device (e.g. will parts of protocol evaluate the effectiveness and/or safety of the device)? <input type="checkbox"/> Yes* <input type="checkbox"/> No</p> <p style="margin-left: 20px;">*If Yes, describe the investigational device procedures (e.g., device has not been approved for marketing, modifications made to an approved device, new investigational use of approved device):</p>

II. DEVICE INFORMATION

3. Has an Investigational Device Exemption (IDE) application been submitted to the FDA for this study?
 Yes* No**

*If Yes, please skip to question #4.

**If No, please check only one box below, and go to question #5.

- a. This study is exempt from IDE regulation under 21 CFR § 812.2(c). **Attach letter explaining why the investigation is exempt.**
- b. The Sponsor contends that the investigational device and its use in the study poses a non-significant risk (NSR) to participants or others, and intends to conduct the study under the abbreviated IDE requirements [21 CFR §812.2(b)].
*The Sponsor requests an Ethics Review Board determination that the study is a NSR device study. **Attach letter from Sponsor stating why test article is NSR.***
- c. The device is a drug delivery system and is being regulated by the FDA under an investigational new drug (IND) application. The IND# is:
- d. Other (*Please explain*):

4. If an IDE application has been submitted to the FDA for this study, complete the following questions:

- a. The Sponsor submitted an IDE application because the Sponsor contends that the investigational device and its use in the study pose a significant risk (SR) to participants or others.
- b. Other (*Please explain*):

On what date was the IDE application submitted to the FDA?

Has the FDA approved an IDE for this study? Yes* No

If Yes*, please provide the IDE #:

II. DEVICE INFORMATION

5. Device class and regulatory controls: Class I Class II Class III N/A

6. Has the FDA conducted a risk assessment of this device? Yes* No

*If Yes, please provide the outcome of the assessment:

7. Is this study being submitted as a 510(k) device study? Yes* No

*If Yes, please provide the 510(k)#:

Attach documentation that this device is substantially equivalent to a marketed device.

III. PERSON COMPLETING FORM

By submitting this form I certify that the information contained is complete and accurate and that no facts have been suppressed or misstated. I am requesting for Total IRB to review the information submitted and provide approval or disapproval information.

Form Completed By _____

Date _____

Title, Company

Phone: _____

Email: _____