For each device used for this research, complete one form and add device labeling, package insert, instruction manual, Investigator Brochure and clinical protocol (as applicable). Submit a copy of all FDA or sponsor documents related to this drug including Investigational Device Exemption (IDE) documentation and device risk determinations. In the protocol, include the risks associated with the use of the device and how those risks will be minimized. Also, address how participants will be instructed in the use of the device and upload corresponding documents.

All clinical investigations of devices must have an approved IDE or be exempt from the IDE regulations. Investigations that are exempted from 21 CFR 812 are described in [§812.2(c)](https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-812/subpart-A/section-812.2#p-812.2(c)) of the IDE regulations. Significant Risk (SR) device projects are governed by the Investigational Device Exemptions (IDE) regulations ([21 CFR Part 812](https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-812)). Non-Significant Risk (NSR) device projects have fewer regulatory controls than SR projects and are governed by the abbreviated requirements (21 CFR [812.2(b)](https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-812/subpart-A/section-812.2#p-812.2(b))). The major differences are in the approval process and in the record keeping and reporting requirements. If a researcher proposes the initiation of a claimed NSR device project to the IRB, and if the IRB agrees that the device project is NSR and approves the project, the project may begin without submission of an IDE application to FDA.

Exempt and abbreviated IDE requirements do not in any way exempt you from complying with FDA requirements including the requirements for informed consent and initial and continuing review conducted by the IRB. You must monitor the research and report to the IRB and FDA noncompliance, adverse events, and unanticipated problems. If abbreviated IDE requirements apply, you will maintain records and reporting according to the requirements at 21 CFR 812.[140](https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-812/subpart-G/section-812.140) and [150](https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-812/subpart-G/section-812.150). You will not promote or test market an investigational device, until after FDA has approved the device for commercial distribution; charge participants for a device beyond recovering costs; unduly prolong the research; nor represent that an investigational device is safe or effective for the purposes for which it is being investigated.

1. Device information

Device name:

Device model number:

Device manufacturer:

Describe each important component, ingredient, property, and principle of operation of the device:

Is the device FDA approved for the proposed use?  Yes  No

Does the device have an Investigational Device Exemption (IDE)?

Yes, specify IDE #:        No

1. Describe how the device is stored securely:
2. Describe how the device is labeled (note that the device must be labeled as an investigational device, see FDA guidance):
3. Describe who has access to the device:
4. Will participants be charged for the device?  Yes  No
5. Describe how will the device be provided or delivered to participants:
6. Describe how will unused devices be disposed of following discontinuation, termination, suspension, or completion of the investigation, include details if the device is surgically implanted:
7. Are you requesting an abbreviated IDE determination?

Yes, complete the abbreviated IDE questions.

No, skip the abbreviated IDE questions.

1. Are you requesting an exemption from IDE requirements?

Yes, complete the IDE Exempted Investigations questions.

No, skip the IDE Exempted Investigations questions.

## Abbreviated IDE

1. Is the device is banned in the United States?  Yes  No
2. What is the risk level of the device?

Significant Risk  Non-Significant Risk

*Use the following questions to determine risk; all answers must be “No” to be considered Non-Significant Risk*

Is it intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a participant?

Yes  No

Is it purported or represented to be for use supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a participant?

Yes  No

Is the device for a use of substantial importance in diagnosing, curing, mitigating, or treating disease or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a participant?

Yes  No

Does the device otherwise presents a potential for serious risk to the health, safety, or welfare of a participant?

Yes  No

Provide a justification why the device does not pose a significant risk:

IDE Exempted Investigations

1. Is it a device, other than a transitional device, in commercial distribution immediately before May 28, 1976, when used or investigated in accordance with the indications in labeling in effect at that time.

Yes, upload supporting documentation  No

1. It is a device, other than a transitional device, introduced into commercial distribution on or after May 28, 1976, that FDA has determined to be substantially equivalent to a device in commercial distribution immediately before May 28, 1976, and that is used or investigated in accordance with the indications in the labeling FDA reviewed under subpart E of part 807 in determining substantial equivalence.

Yes, upload supporting documentation  No

1. Is it a diagnostic device, where the sponsor complies with applicable requirements in § 809.10(c) and the testing: is noninvasive, does not require an invasive sampling procedure that presents significant risk, does not by design or intention introduce energy into a subject, and is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure?

Yes, upload supporting documentation  No

1. Is it a device undergoing consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution, if the testing is not for the purpose of determining safety or effectiveness and does not put participants at risk.

Yes, upload supporting documentation  No

1. It is a device intended solely for veterinary use.

Yes, upload supporting documentation  No

1. Is it a device shipped solely for research on or with laboratory animals and labeled in accordance with § 812.5(c).

Yes, upload supporting documentation  No

1. Is it a custom device as defined in § 812.3(b), unless the device is being used to determine safety or effectiveness for commercial distribution.

Yes, upload supporting documentation  No