The purpose of this form is to determine whether use of the device in a clinical investigation is exempt from the FDA requirement to obtain an Investigational Device Exemption (IDE) prior to beginning research. Based on the information you provide in this form, you may be directed to obtain an IDE from the FDA.

* Clinical Investigation: Any experiment that involves a test article and one or more human subjects.
* Device: Intended for use in the diagnosis of disease or other condition, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.
* Diagnostic Device: Those reagents, instruments, and systems intended for use in diagnosis of disease or other conditions, including determination of the state of health in order to cure, mitigate, treat, or prevent disease or its sequelae.
* Investigational Device: The device is the purpose of the investigation and will be used to evaluate safety or effectiveness in the diagnosis of disease or other conditions; or the cure, mitigation, treatment, or prevention of disease.
* In-Vitro Diagnostic: Those reagents, instruments, and systems intended for use in diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body.
* Software as Medical Device: Software intended to be used for one or more medical purposes without being part of a hardware medical device.

Note: Devices may be used in research but may not be the purpose of the investigation (e.g., as an adjunct to a standard procedure or test for screening). Information about these devices must be included in the *IRB Application for Human Subjects Research*, so an assessment of risk and safety to subjects can be made. If the device is not the purpose of the investigation, it is not necessary to complete this form.

Instructions:

* Proceed through the form from the beginning and follow the listed flow instructions carefully.
* Complete a separate *Appendix for Devices* for each device listed in the eIRB system, as applicable.
* Provide the device manual in the eIRB system showing the device’s cleared indications.

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| **Basic Information** | |
| **Title of Study:** |  |
| **Short Title:** |  |
| **Principal Investigator Name:** |  |

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| Section 1: General Questions | | |
| Device name: | | |
| Device manufacturer: | | |
| Section 2: IDE Status | | |
| Does the device have an approved IDE from FDA?  If Yes, STOP HERE and upload documentation of the IDE number (e.g., FDA or sponsor correspondence) to eIRB. Provide the IDE number: | | Yes No |
| Section 3: IDE Exemptions  Only ONE of the items listed below should apply to the device under investigation | | |
| 1. Is this a lawfully marketed device (i.e., subject of an FDA cleared 510(k) or premarket approval application (PMA), which is unchanged from its approved or cleared form?  If Yes, use of the device is exempt from the IDE requirements. STOP HERE – this form is complete. | | Yes No |
| 2. Is the device a non-invasive ([21 CFR 812.3(k)](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.3)) diagnostic device ([21 CFR 812.2(3)](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=812&showFR=1))?  *A non-invasive device or procedure is one that does not by design or intention: (1) penetrate or pierce the skin or mucous membranes of the body, the ocular cavity, or the urethra, or (2) enter the ear beyond the external auditory canal, the nose beyond the nares, the mouth beyond the pharynx, the anal canal beyond the rectum, or the vagina beyond the cervical os. If you are obtaining samples by one of the methods listed in 1 or 2 above, the test IS invasive, and you should answer NO.*  *A diagnostic device:*   1. *Is Non-invasive,* 2. *Does not require an invasive sampling procedure that presents significant risk,* 3. *Does not by design or intention introduce energy into a subject, and* 4. *Is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.*   If Yes, use of the device is exempt from the IDE requirements. STOP HERE – this form is complete. | | Yes No |
| 3. Does the study involve a device undergoing consumer preference testing, testing of a modification of an approved or cleared device, or testing of a combination of two or more devices currently in commercial distribution?  *Testing cannot be for the purpose of determining the safety or effectiveness of the device or combination nor can testing put subjects at risk.*  If Yes, use of the device is exempt from the IDE requirements. STOP HERE – this form is complete. | | Yes No |
| 4. Does the device meet the definition of a custom device?  *Custom devices are used for the purpose of treating a rare condition, such that conducting clinical investigations on such devices would be impractical. Production of custom devices is limited to no more than 5 units per year of a particular device type. In general, a custom device:*   * *Necessarily deviates from devices generally available or from an applicable performance standard or premarket approval requirement in order to comply with the order of an individual physician or dentist;* * *Is not generally available to, or generally used by, other physicians or dentists;* * *Is not generally available in finished form for purchase or for dispensing upon prescription;* * *Is not offered for commercial distribution through labeling or advertising;* ***and*** * *Is intended for use by an individual patient named in the order of a physician or dentist, and is to be made in a specific form for that patient, or is intended to meet the special needs of the physician or dentist in the course of professional practice.*   **If Yes, use of the device is exempt from the IDE requirements. STOP HERE – this form is complete.**  **If No, proceed to Section 4.** | | Yes No |
| Section 4: Significant Risk (SR) Determination | | |
| *The use of the device in this study is not exempt from the FDA requirement to obtain an Investigational Device Exemption (IDE).*  *If the IRB determines that the device is nonsignificant risk (NSR), the study may proceed under abbreviated IDE requirements. An IDE submission to the FDA is not required under the abbreviated requirements, but the requirements for labeling, informed consent, monitoring, records and reports, promotional practices, clinical investigator disqualification, and IRB review requirements contained in FDA regulations still apply (*[*21 C.F.R § 812.2(b)*](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.2)*).*  *For details on the definition of significant risk devices, see the* [*FDA Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors: Significant Risk and Nonsignificant Risk Medical Device Studies.*](https://www.fda.gov/media/75459/download) | | |
| 1. Does the use of the device in this study meet ANY of the following criteria?  If Yes to ANY categories below, the device is a Significant Risk (SR) device and approval from the FDA must be sought.  If No to ALL categories below, proceed to Section 5*.* | | |
| 1. Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject.   If Yes, explain: | Yes No | |
| 1. Is purported or represented to be for a use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject.   If Yes, explain: | Yes No | |
| 1. Is 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 subject.   If Yes, explain: | Yes No | |
| 1. Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.   If Yes, explain: | Yes No | |
| Section 5: Nonsignificant Risk (NSR) Determination | | |
| 1. Does the device present a potential for serious risk or harm?  Explain: | | |
| 2. What are the possible risks to a study participant as compared to standard care, risks due to design of the device, or other risks related to use of the device?  Explain: | | |