OFFICE OF RESEARCH REGULATORY AFFAIRS
DEVICE RISK DETERMINATION CHECKLIST FOR REVIEWERS

Investigator: **IRB #:**

Study Title:

Device(s):

The following documents were used in this evaluation:

- ☐ Protocol / Investigational Plan
- ☐ Informed Consent
- ☐ Premarket Notification 510(k) Clearance/Premarket Approval (PMA)/De Novo
- ☐ Supporting literature
- ☐ Device manual(s)
- ☐ Other:_____

Device *(Section 201(h)), FD&C Act; 21 USC 321(h)):* An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

- Recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them, or
- Intended for use in the diagnosis of disease or other conditions, 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 not dependent upon being metabolized for the achievement of its primary intended purposes.

NOTE: The term 'device' does not include software functions excluded pursuant to Section 520(o) of the FD&C Act; 21 USC 360j(A)(o)).

Does the study include a *device*? If not, 21 CFR 812 does not apply to the study. ☐ Yes ☐ No

Is the device(s) being evaluated for safety and/or effectiveness? If not, the device(s) is not an *investigational device*, and 21 CFR 812 does not apply to the study. ☐ Yes ☐ No

Other Definitions: [21 CFR 812.3]

- *Custom Device (21 USC 360j(b) excerpt)* - (1)(A) is created or modified in order to comply with the order of an individual physician… (E)(ii) is intended for use by an individual patient named in such order of such physician… (2)(B) production of such device under paragraph (1) is limited to no more than 5 units per year of a particular device type...
- *Implant* - a device that is placed into a surgically or naturally formed cavity of the human body if it is intended to remain there for a period of 30 days or more. FDA may, in order to protect public health, determine that devices placed in subjects for shorter periods are also “implants” for purposes of this part.
- *Investigation* - a clinical study or research involving one or more subjects to determine safety or effectiveness of a device.
- *Investigational device* - a device, including a transitional device, that is the object of an investigation.
- *Noninvasive* - diagnostic device or procedure 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. Blood sampling that involves simple venipuncture is considered noninvasive, as is the use of surplus samples of body fluids or tissues that are left over from samples taken for noninvestigational purposes.
- *Predicate device* - legally marketed device
- *Subject* - a human who participates in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control. A subject may be in normal health or have a medical condition or disease.
- *Substantially Equivalent* - new device is considered as safe and effective as the predicate device.
- *Transitional device* - a device subject to section 520(l) of the act that was regulated by the FDA as a new drug or an antibiotic drug before May 28, 1976.

The device is *exempt* from the IDE regulations if (at least) ONE of the following is true:

☐ **Exemption (1)** - The following is true: [21 CFR 812.2(c)(1)]

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.

☐ **Exemption (2)** - The following is true: [21 CFR 812.2(c)(2)]

A device, other than a transitional device, introduced into commercial distribution on or after May 28, 1976, that the FDA 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.

☐ **Exemption (3)** - In the case of a ***diagnostic device*** where ALL of the following are true: [21 CFR 812.2(c)(3)]

Sponsor complies with applicable requirements in 21 CFR 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.

☐ **Exemption (4)** - The following is true: [21 CFR 812.2(c)(4)]

A device undergoing either consumer preference testing, the testing of a modification, or the 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 subjects at risk.

☐ **Exemption (5)** - The following is true: [21 CFR 812.2(c)(5)]

The device is intended solely for veterinary use.

☐ **Exemption (6)** - The following is true: [21 CFR 812.2(c)(6)]

The device is shipped solely for research on or with laboratory animals and labeled in accordance with §812.5(c).

☐ **Exemption (7)** - The following is true: [21 CFR 812.2(c)(7)]

The device is a custom device as defined in 21 CFR 812.3(b), unless the device is being used to determine safety or effectiveness for commercial distribution.

A non-exempt device will require a *Significant Risk* (SR) or a *Non-Significant Risk* (NSR) IDE.

☐ **Significant Risk Device** - (at least) ONE of the following is true: [21 CFR 812.3(m)]

The investigational device is a significant risk device because the device:
- ☐ Is intended as an implant that presents a potential for serious risk to the health, safety, or welfare of a subject;
- ☐ 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;
- ☐ Is 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 subject;
- ☐ Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

☐ **Non-Significant Risk Device** [21 CFR 812.2(b)]

The investigational device is a non-significant risk device because the device does not meet any of the criteria for a significant risk device or device exemption and is not a banned device.

Reviewer's Evaluation:

- ☐ The study does not include a *device*.
- ☐ The device(s) is not being evaluated for safety and/or effectiveness and therefore does not meet the definition of an *investigational device*.
- ☐ The investigation is exempt from IDE regulations.
- ☐ The device(s) in this investigation is a *non-significant risk* device; an NSR IDE is required.
- ☐ The device(s) in this investigation is a *significant risk* device; an SR IDE is required.
- ☐ Risk could not be determined; a Study Risk Determination should be requested from the FDA.
- ☐ Other (explain below)

Comments:

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Final Reviewer Decision:

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Reviewer Signature: **Date:**