Investigator/Sponsor should use the Q Submission process to contact the FDA with questions as to whether a product is a medical device, exempt from IDE regulations, or an NSR submission.

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program>

IS THE MEDICAL DEVICE NON-SIGNIFICANT RISK (NSR)?

An NSR device:

*• Is NOT intended as an implant and does NOT present a potential for serious risk to the health, safety, or welfare of a subject;*

*Is NOT purported or represented to be for a use in supporting or sustaining human life and does NOT present a potential for serious risk to the health, safety, or welfare of a subject;*

*• Is NOT for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and does NOT present a potential for serious risk to the health, safety, or welfare of a subject; or*

*• does NOT otherwise present a potential for serious risk to the health, safety, or welfare of a subject.*

Select IDE exempt in 3.5 AND

In a memo in AURA View 8.1, confirm that the device meets exemption criteria listed above.

YES

NO

IS IT EXEMPT FROM IDE REQUIREMENTS?

A diagnostic device is exempt if it

* *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 by another medically established diagnostic product or procedure*

In a memo in AURA View 8.1, please confirm that the product is not a medical device per FDA definition.

NO

In 3.5 select not exempt, no IDE and in memo in View 8.1, confirm that device meets aforementioned criteria. **Ask IRB to confirm that it’s Non-Significant Risk –or** provide official FDA determination if available.

This device study qualifies as Significant Risk. Please contact FDA. If IDE is obtained, please provide IDE # and IDE letter from FDA.

NO

YES

YES, select “use of device” in view 2.2. If the device is not approved, then consider if it is exempt.

IS IT A MEDICAL DEVICE?

*FDA definition: "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 Pharmacopoeia, or any supplement to them,*
* *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 which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."*