SPECTRUM HEALTH	**CHECKLIST:** Non-Significant Risk Device			**IRB #**
	NUMBER	**DATE**	**PAGE**	**Review Type:**
	HRP-424	01/01/2015	1 of 1	**Status:**

The purpose of this checklist is to provide support for the convened IRB when initially evaluating whether a device meets the abbreviated IDE requirements. This checklist must be used for all relevant subsequent reviews (i.e., Modifications, Continuing Reviews).

The convened IRB completes the corresponding section of the TEMPLATE MINUTES to document determinations required by the regulations along with protocol specific findings justifying those determinations, in that case this checklist does not need to be completed or retained, but can be used as a reference during the convened meeting, as needed.

1 SIGNIFICANT RISK DEVICE: (One or more are **"Yes"**)	
☐ **Yes** ☐ **No**	Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject.
☐ **Yes** ☐ **No**	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.
☐ **Yes** ☐ **No**	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.
☐ **Yes** ☐ **No**	Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.
2 NON-SIGNIFICANT RISK DEVICE	
☐ **Yes** ☐ **No**	Meets none of the above criteria.
3 RATIONALE (Describe)	