Study Nickname

**List all specifically-named (“brand name”), non-generic** [**medical devices**](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051512.htm) **(investigational or non-investigational) REQUIRED by the study:**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Name/Description of Device** | [**FDA Device Type**](https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm504091.pdf)  **(select from drop-down)** | **FDA # (for IDE or CAS only)** | **Funding Source**  **(select from drop-down)** | **Location of Device Use**  **(select from drop-down)** | **Does Shands Need to Purchase/Receive?** | **Storage Location**  **(select from drop-down)** |
|  |  |  |  |  | \*\*YES  NO |  |
|  |  |  |  |  | \*\*YES  NO |  |
|  |  |  |  |  | \*\*YES  NO |  |
|  |  |  |  |  | \*\*YES  NO |  |
|  |  |  |  |  | \*\*YES  NO |  |
|  |  |  |  |  | \*\*YES  NO |  |
| **Other Reviews/Policies That May Apply to Your Device**  **\* FDA and Medicare Requirements for IDE and CAS Device Studies**  Any [Investigational Device Exemption (IDE](https://clinicalresearch.ctsi.ufl.edu/services/coverage-analysis/device-studies/ide/)) or [Carotid Artery Stenting (CAS](https://clinicalresearch.ctsi.ufl.edu/services/coverage-analysis/device-studies/cas/)) device study that involves **billing study participants or their insurance** **MUST** be [pre-approved by Medicare](https://clinicalresearch.ctsi.ufl.edu/services/coverage-analysis/device-studies/cas/) prior to enrolling patients. For details, see <https://clinicalresearch.ctsi.ufl.edu/services/coverage-analysis/device-studies/>. **CMS approval letter is a REQUIRED document at Intake Submission.**  \*\* **Shands Requirements**  [Contact Shands Supply Chain Services](https://clinicalresearch.ctsi.ufl.edu/resources/uf-health-research-contacts/shands-supply-chain/) for any device that will be purchased, received, or stored by Shands Hospital.  [Use the Device Trial Listserv](https://clinicalresearch.ctsi.ufl.edu/services/coverage-analysis/device-studies/#ListServ) prior to the implant or use of any IDE or CAS study device in any Shands OR location via [Device-Trials-L@LISTS.UFL.EDU](mailto:Device-Trials-L@LISTS.UFL.EDU).  [Contact Shands Clinical Engineering](https://clinicalresearch.ctsi.ufl.edu/resources/uf-health-research-contacts/shands-clinical-engineering-research-equipment-inspections/) to arrange an inspection for any non-Shands-owned equipment that will be used in Shands clinical areas.  [Contact Shands Radiology](https://clinicalresearch.ctsi.ufl.edu/resources/uf-health-research-contacts/radiology-inspections/) for special requirements related to non-Shands-owned **radiologic devices or equipment** that will be used in Shands clinical areas. | | | | | | |

**Comments:**