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ClearPoint Neuro, Inc. Indications for Use (K142505): *The ClearPoint® System is intended to provide stereotactic guidance for the placement and operation of instruments or devices during planning and operation of neurological procedures within the MRI environment and in conjunction with MR imaging. The ClearPoint System is intended as an integral part of procedures that have traditionally used stereotactic methodology. These procedures include biopsies, catheter and electrode insertion including deep brain stimulation (DBS) lead placement. The System is intended for use only with 1.5 and 3.0 Tesla MRI scanners and MR Conditional implants and devices. The user should consult the “Navigational Accuracy” section of the User’s Guide to assess if the accuracy of the system is suitable for their needs.*

The SmartFlow® MR Compatible Ventricular Cannula has received 510(k) clearance from the FDA for use in the US for the aspiration of CSF or injection of the chemotherapy drug, Cytarabine, into the ventricle.