Safety as defined in (21 CFR § 860.7(d) (1))

There is reasonable assurance that a device is safe when it can be determined, based upon valid scientific evidence, that the probable benefits to health from use of the device for its intended uses and conditions of use, when accompanied by adequate directions and warnings against unsafe use, outweigh any probable risks.

Effectiveness as defined in (21 CFR § 860.7(e)(1))

There is reasonable assurance that a device is effective when it can be determined, based upon valid scientific evidence, that in a significant portion of the target population, the use of the device for its intended uses and conditions of use, when accompanied by adequate directions for use and warnings against unsafe use, will provide clinically significant results.

Indication for Use

The proposed indications for use, submitted by the sponsor, as stated in the PMA, are as follows: The ISS500 is indicated to increase cerebral blood flow and reduce disability in adult patients with acute ischemic stroke with confirmed cortical involvement in the anterior circulation who are ineligible or have no access to IV-tPA and endovascular thrombectomy. Treatment is to be initiated between 8 and 24 hours from stroke onset (last known well).

Voting Question 1
Safety

Is there reasonable assurance that the BrainsGate Ischemic Stroke System (ISS500) is safe for use in patients who meet the criteria specified in the proposed indication?

Voting Question 2
Effectiveness

Is there reasonable assurance that the BrainsGate Ischemic Stroke System (ISS500) is effective for use in the patients who meet the criteria specified in the proposed indication?

Voting Question 3
Benefit-Risk

Do the benefits of the BrainsGate Ischemic Stroke System (ISS500) outweigh the risk for use in the patients who meet the criteria specified in the proposed indication?