Voting Questions

Neurological Devices Panel of the Medical Devices Advisory Committee

The Medical Device Amendments to the Federal Food, Drug and Cosmetic Act, as amended by the Safe Medical Devices Act of 1990, allow the Food and Drug Administration to obtain a recommendation from an expert advisory panel on designated medical device premarket applications (PMAs) that are filed with the Agency. The PMA must stand on its own merits and your recommendation must be supported by safety and effectiveness data in the application or by applicable publicly available information.

Definitions of Safety and Effectiveness:

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."

The applicant has proposed the following Indication for Use:

> **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 8-24 hours from stroke onset (last known well).**

The following Voting Questions relate to the approvability of the BrainsGate Ischemic Stroke System (ISS500) by BrainsGate Ltd. Please answer them based on your expertise, the information you reviewed in preparation for this meeting, and the information presented.

Voting Question 1:

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:

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:

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?

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