Voting Questions

Circulatory System Devices Panel of the Medical Devices Advisory Committee

V-Wave Ventura Interatrial Shunt System

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 Ventura Shunt is indicated for NYHA Class III heart failure patients who remain symptomatic despite guideline-directed medical therapy, have a LVEF of ≤40%, and who are judged by a Heart Team to be appropriate for Shunt therapy, to reduce the risk of hospitalization for heart failure.**

The following Voting Questions relate to the approvability of the V-Wave Ventura Interatrial Shunt System. 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 V-Wave Ventura Interatrial Shunt System is safe for use in patients who meet the criteria specified in the proposed indication?

Voting Question 2:

Is there reasonable assurance that the V-Wave Ventura Interatrial Shunt System is effective for use in the patients who meet the criteria specified in the proposed indication?

Voting Question 3:

Do the benefits of the V-Wave Ventura Interatrial Shunt System outweigh the risk for use in the patients who meet the criteria specified in the proposed indication?