Voting Questions
for the
Circulatory System Devices Advisory Panel
July 20, 2011
P100041

Edwards SAPIEN Transcatheter Heart Valve, model 9000TFX, sizes 23mm and 26mm and accessories (RetroFlex 3™ Delivery System, models 9120FS23 and 9120FS26; RetroFlex™ Balloon Catheter, models 9120BC20 and 9120BC23; and Crimper, models 9100CR23 and 9100CR26)

The sponsor has proposed the following Indications for Use:
“The Edwards SAPIEN Transcatheter Heart Valve, model 9000TFX, sizes 23mm and 26mm, and RetroFlex 3 Delivery System are indicated for transfemoral delivery in patients with severe aortic stenosis who have been determined by a cardiac surgeon to be inoperable for open aortic valve replacement and in whom existing co-morbidities would not preclude the expected benefit from correction of the aortic stenosis.

The RetroFlex Balloon Catheter is indicated for pre-dilatation of a stenotic cardiac valve prior to implantation of a transcatheter heart valve.

The Crimper is indicated for preparing the Edwards SAPIEN Transcatheter Heart Valve for implantation.”

The following questions relate to the approvability of the Edwards SAPIEN™ Transcatheter Heart Valve. Please answer them based on your expertise, the information you reviewed in preparation for this meeting, and the information presented today.

Voting Question 1:
Is there reasonable assurance that the Edwards SAPIEN™ Transcatheter Heart Valve is safe for use in patients with severe aortic stenosis who have been determined by a cardiac surgeon to be inoperable for open aortic valve replacement and in whom existing co-morbidities would not preclude the expected benefit from correction of the aortic stenosis?

Voting Question 2:
Is there reasonable assurance that the Edwards SAPIEN™ Transcatheter Heart Valve is effective for use in patients with severe aortic stenosis who meet the criteria specified in the proposed indication?

Voting Question 3:
Do the benefits of the Edwards SAPIEN™ Transcatheter Heart Valve for use in patients with severe aortic stenosis who meet the criteria specified in the proposed indication outweigh the risks of the Edwards SAPIEN™ Transcatheter Heart Valve for use in patients with severe aortic stenosis who meet the criteria specified in the proposed indication?