

ANESTHESIOLOGY AND RESPIRATORY THERAPY DEVICES PANEL OF THE MEDICAL DEVICES ADVISORY COMMITTEE

PneumRx, Inc. Elevair™ Endobronchial Coil System

Gaithersburg Holiday Inn 2 Montgomery Village Ave., Gaithersburg, MD Grand Ballroom

June 14, 2018

08:00 a.m. Call to Order Panel Introductions

Conflict of Interest Statement

Steven Nathan, MD Chairperson

Evella Washington Designated Federal Officer

- 08:15 a.m. Sponsor Presentation
- 09:45 a.m. Sponsor Q&A
- 10:00 a.m. Break
- 10:15 a.m. FDA Presentation
- 11:45 a.m. FDA Q&A
- 12:00 pm Lunch
- 1:00 p.m. Open Public Hearing*
- 2:00 p.m. Panel Deliberations
- 3:15 p.m. Break
- 3:30 p.m. FDA Questions to the Panel
- 5:00 p.m. FDA and Sponsor Summations
- 5:20 p.m. Panel Vote

6:00 p.m. Adjournment

* **Open Public Hearing** – Interested persons may present data, information, or views, orally or in writing, on the issue pending before the panel. Scheduled speakers who have requested time to address the panel will speak at this time. After they have spoken, the Chair may ask

them to remain if the panel wishes to question them. Then the Chair will recognize unscheduled speakers as time allows. Only the panel may question speakers during the open public hearing.