



**CIRCULATORY SYSTEM DEVICES PANEL
OF THE
MEDICAL DEVICES ADVISORY COMMITTEE**

**GENERAL ISSUES MEETING RELATING TO
DEVICE BASED THERAPIES FOR HYPERTENSION
DECEMBER 5, 2018**

Panel Chairperson
Richard A. Lange, MD

Designated Federal Officer
Patricio G. Garcia, M.P.H.

- 8:00 a.m. Call to Order**
Introduction of Committee
Conflict of Interest Statement
- Agency Presentation*
- 8:15 a.m. Center for Devices and Radiological Health**
- 9:00 a.m. Clarifying Questions from the Panel**
- 9:15 a.m. Break**
- Manufacturer Presentations*
- 9:30 a.m. Medtronic**
- 10:10 a.m. ReCor Medical**
- 10:50 a.m. ROX Medical**
- 11:10 a.m. Vascular Dynamics**
- 11:30 a.m. Clarifying Questions from the Panel**
- 12:00 p.m. Lunch**
- 1:00 p.m. Open Public Hearing**
- 2:00 p.m. FDA Questions/Panel Deliberations**
- 3:30 p.m. Break**
- 3:45 p.m. FDA Questions/Panel Deliberations Continued**
- 5:30 p.m. Summary of Panel Recommendations**
- 6:00 p.m. Adjourn**



*** 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.