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.