



Circulatory System Devices Panel for the Medical Devices Advisory Committee August 23, 2023

Discuss, make recommendations, and vote on information regarding the premarket approval application (PMA) for the Medtronic Inc. Symplicity Spyrax Renal Denervation System

Panel Chairperson:
Richard Lange, M.D.

Designated Federal Officer:
Jarrod Collier, M.S.

9:00 a.m.	Call to Order Panel Introductions Conflict of Interest
9:30 a.m.	Medtronic Presentation (75 min)
10:45 a.m.	Questions to Medtronic (15 min)
11:00 a.m.	Break (15 min)
11:15 a.m.	FDA Presentation (75 min)
12:30 p.m.	Questions to FDA (15 min)
12:45 p.m.	Lunch (45 min)
01:30 p.m.	Open Public Hearing* (60 min)
02:30 p.m.	Panel Deliberation (60 min)
03:30 p.m.	Break (15 min)
03:45 p.m.	FDA Questions (75 min)
05:00 p.m.	Vote (15 min)
05:45 p.m.	Summary of Panel Recommendations (15 min)
06:00 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.