

AGENDA

CIRCULATORY SYSTEM DEVICES PANEL of the MEDICAL DEVICES ADVISORY COMMITTEE

Hilton Washington DC North/Gaithersburg

June 2, 2016

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| 8:00 a.m. | Call to Order
Introduction of Committee | Richard A. Lange, MD
Chairperson |
| | Conflict of Interest Statement | Evella F. Washington
Designated Federal Officer |
| 8:15 a.m. | Center for Devices and Radiological Health
Part I: Welcome and Introduction
Suzanne Schwartz, MD, MBA | |
| | Part II: Overview of Heater-Cooler Devices
Nicole Milligan | |
| | Part III: HCD Validation: Cleaning & Disinfection
Elaine S. Mayhall, PhD | |
| | Part IV: Investigations
Julia Marders, RN, MS | |
| | Part V: Medical Device Reports (MDRs)
Kelly Bauer, RN, BSN | |
| | Part VI: Information Request (IR) Letters
Kelly Bauer, RN, BSN | |
| 9:45 a.m. | Clarifying Questions from the Panel | |
| 10:15 a.m. | Break | |

AGENDA, continued

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- 10:30 a.m. Sorin LivaNova
Thierry Dupoux
Christian Peis
Paul Talbot, M.S.
Brian Duncan, M.D.
- 10:50 a.m. Cincinnati Sub-Zero Products, LLC
Steve Berke
Christina Miracle
Dan Wittmer
- 11:10 a.m. CardioQuip
Douglas E. Platt
Jon L. Gardner
- 11:30 a.m. Clarifying Questions from the Panel
- 12:00 p.m. **Lunch**
- Open Public Hearing*
- 1:00 p.m. *Speaker 1:* Penn State Milton S. Hershey Medical Center
Dr. Carol Freer
Dr. Cindy Whitener
- 1:30 p.m. *Speaker 2:* Stryker Medical
Brian Orwat- Senior Staff RA Specialist (presenter)
Gregg Taylor
Eric Varty
- 2:00 p.m. Clarifying Questions from the Panel
- 2:15 p.m. Nontuberculous Mycobacteria and Heater-Coolers
Joseph O. Falkinham, III, Ph.D.
- 2:40 p.m. OR Environment
Sylvia Munoz-Price, M.D., Ph.D.
- 3:10 p.m. **Break**

AGENDA, continued

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- 3:25 p.m. Chimaera – Zurich, Switzerland: Where it all started.
Hugo Sax, M.D.
- 3:55 p.m. Heater Cooler Unit Infection Risks: Perspective from CDC
Joseph F. Perz, DrPH, MA
- 4:25 p.m. State of PA Investigation
Jeff Miller, M.D.
- 4:55 p.m. Clarifying Questions from the Panel
- 5:25 p.m. Session 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. The Chair may recognize unscheduled speakers if time allows. Only the Panel may question speakers during the Open Public Hearing. Public attendees may not participate except at the specific request of the Panel Chair.