AGENDA

CIRCULATORY SYSTEM DEVICES PANEL
of the
MEDICAL DEVICES ADVISORY COMMITTEE

Hilton Washington DC North/Gaithersburg

June 2, 2016

8:00 a.m.  Call to Order  Richard A. Lange, MD
Introduction of Committee  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. Falkingham, 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.