AGENDA

GENERAL AND PLASTIC SURGERY DEVICES PANEL
OF THE
MEDICAL DEVICES ADVISORY COMMITTEE

Hilton Washington DC North/Gaithersburg

September 21, 2016

8:00 a.m. Call to Order
Hobart W. Harris, M.D.
Introduction of Committee
Chairperson

Evella F. Washington
Designated Federal Officer

8:15 a.m. Day 1 Summary and Clarifying Questions from the Panel
Cynthia Chang, Ph.D., Division of Surgical Devices

8:30 a.m. Classification Presentation
Angela DeMarco, Premarket Notification (510K) Program (on detail)

8:45 a.m. Clarifying Questions from the Panel

9:00 a.m. Open Public Hearing*

10:30 a.m. Break

10:45 a.m. Proposed classification table and risk mitigations/proposed controls
Cynthia Chang, Ph.D., Division of Surgical Devices

11:30 a.m. Clarifying Questions from the Panel

11:40 a.m. Panel Deliberations and FDA Classification Questions
Part 1: Classification questions – Solid Dressings
Cynthia Chang, Ph.D., Division of Surgical Devices

12:15 p.m. Lunch

1:15 p.m. Panel Deliberations and FDA Classification Questions-continued
Part 2: Classification questions – Wound Dressings in the form of Creams/Gels/Ointments
Cynthia Chang, Ph.D., Division of Surgical Devices
AGENDA, continued

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Part 3: Classification questions – Liquid wound washes
Cynthia Chang, Ph.D., Division of Surgical Devices

3:15 p.m.  Break

3:30 p.m.  Panel Deliberations and FDA Classification Questions - continued

4:30 p.m.  Final Remarks

5:00 p.m.  Meeting 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.