



AGENDA

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

Hilton Washington DC North/Gaithersburg

September 21, 2016

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|------------|---|--|
| 8:00 a.m. | Call to Order
Introduction of Committee | Hobart W. Harris, M.D.
Chairperson |
| | Conflict of Interest Statement | 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. | <i>Open Public Hearing*</i> | |
| 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
<i>Part 1: Classification questions – Solid Dressings</i>
Cynthia Chang, Ph.D., Division of Surgical Devices | |
| 12:15 p.m. | Lunch | |
| 1:15 p.m. | Panel Deliberations and FDA Classification Questions-continued
<i>Part 2: Classification questions – Wound Dressings in the form of Creams/Gels/Ointments</i>
Cynthia Chang, Ph.D., Division of Surgical Devices | |

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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.