



**CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES PANEL
OF THE
MEDICAL DEVICES ADVISORY COMMITTEE**

Baebies, Seeker Newborn Screening System

August 10, 2016

Panel Chairperson

Karol E. Watson, M.D., Ph.D.

Designated Federal Officer

Patricio G. Garcia, M.P.H.

08:00 a.m. Call to Order
Panel Introductions
Conflict of Interest Statements

08:15 a.m. Sponsor Presentation

09:45 a.m. Q&A Sponsor

10:00 a.m. Break

10:15 a.m. FDA Presentation

11:45 a.m. Q&A FDA

12:00 pm Lunch

1:00 p.m. Open Public Hearing*

2:00 p.m. Panel Deliberations

3:00 p.m. Break

3:15 p.m. FDA Questions

5:30 p.m. FDA and Sponsor Summations

6:00 p.m. 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. Then the Chair will recognize unscheduled speakers as time allows. Only the panel may question speakers during the open public hearing.