



**GASTROENTEROLOGY AND UROLOGY DEVICES PANEL
of the
MEDICAL DEVICES ADVISORY COMMITTEE**

**Ablatherm® HIFU System
July 30, 2014**

Panel Chairperson
Mark Talamini, M.D.

Designated Federal Officer
LCDR S. J. Anderson, MPH

08:00 a.m.	Call to Order Panel Introductions Conflict of Interest Statements
08:30 a.m.	Sponsor Presentation
09:45 a.m.	Q&A Sponsor
10:00 a.m.	Break
10:15 a.m.	FDA Presentation
11:30 a.m.	Q&A FDA
12:00 pm	Lunch
01:00 p.m.	Open Public Hearing*
02:00 p.m.	Panel Deliberations
03:00 p.m.	Break
03:15 p.m.	FDA Questions
05:30 p.m.	FDA and Sponsor Summations
05:40 p.m.	Panel Vote
06:00 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.