



**FDA CDRH
Radiological Devices Panel of the Medical
Devices Advisory Committee**

**November 7, 2023
Virtual**

The committee will discuss and make recommendations on the classification proposals blood irradiator devices intended to be used for the irradiation of intra-operatively salvaged blood for cancer patients undergoing surgery to assist in the prevention of metastasis.

9:00 a.m.	Call to Order, Opening Remarks, and Introduction of the Committee	John Carrino, M.D., Ph.D. Panel Chair
9:10 a.m.	Conflict of Interest Statement	Jarrold Collier, M.S. Designated Federal Officer
9:20 a.m.	Open Public Hearing*	
10:20 a.m.	FDA Presentation — “Device Classification”	FDA Regulatory Policy Group
10:30 a.m.	FDA Presentation — “Classification of Blood Irradiators for the Prevention of Metastasis”	Justina Tam, Ph.D.
10:55 a.m.	Clarifying Questions from Panel	Panel Chair
11:05 a.m.	BREAK	
11:15 a.m.	Panel Questions and Deliberations	Panel Chair
12:00 p.m.	Panel Summation	Panel Chair
12:15 p.m.	Adjourn	Panel Chair

*** 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.