



## AGENDA

### The General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee

November 7, 2024

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*The Committee will discuss the clinical performance data gathered on the IceCure ProSense Cryoablation System, provide recommendations, and vote on information relative to the benefits and risks profile for a De Novo marketing submission of the IceCure ProSense Cryoablation System.*

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9:00 a.m.	<b>Call to Order Panel Introductions</b>	<b>Hobart Harris, M.D., M.P.H.</b> Panel Chair
	<b>Conflict of Interest Statement</b>	<b>Candace Nalls, M.P.H.</b> Designated Federal Officer
9:20 a.m.	<b>External Speakers</b>	<b>Monica Morrow, M.D., F.A.C.S.</b> Memorial Sloan Kettering Cancer Center <b>Julie A. Margenthaler, M.D., F.A.C.S.</b> Washington University School of Medicine <b>Patricia A. Ganz, M.D.</b> UCLA School of Medicine
10:35 a.m.	<b>Break (10 min)</b>	
10:45 a.m.	<b>IceCure Medical Ltd. Presentation</b>	<b>Shay Levav, IceCure Medical</b> <b>Nathalie Johnson, M.D., F.A.C.S.,</b> Legacy Cancer Institute <b>Robert Carlton Ward, M.D.,</b> Warren Alpert Medical School of Brown University <b>Richard E. Fine, M.D., F.A.C.S.,</b> Margaret West Comprehensive Breast Center, WCC & RI

**Margeaux Rogers, M.S., RAC,**  
MCRA, LLC, an IQVIA business

11:45 p.m.	<b>Questions for IceCure Medical Ltd.</b>	
12:00 p.m.	<b>FDA Presentation</b>	<b>Jessica Carr, Ph.D.,</b> OHTIV, CDRH <b>Jinfeng Tian, Ph.D.,</b> OHTIV, CDRH <b>Steven Nagel, M.D., F.A.C.S.,</b> OHTIV, CDRH <b>Xu Zhang, Ph.D.,</b> OHTIV, CDRH <b>Areej Idris, B.S. Pharm, M.P.H,</b> OHTIV, CDRH
1:00 p.m.	<b>Questions for FDA</b>	
1:15 p.m.	<b>Lunch</b>	
2:15 p.m.	<b>Open Public Hearing*</b>	
3:15 p.m.	<b>Panel Deliberations</b>	
4:15 p.m.	<b>Break (10 min)</b>	
4:25 p.m.	<b>FDA Questions to the Panel</b>	<b>Hobart Harris, M.D., M.P.H.</b> Panel Chair
5:25 p.m.	<b>FDA and Sponsor Summation</b>	<b>Hobart Harris, M.D., M.P.H.</b> Panel Chair
5:45 p.m.	<b>Vote</b>	<b>Candace Nalls, M.P.H.</b> Designated Federal Officer
6:00 p.m.	<b>Adjourn</b>	<b>Hobart Harris, M.D., M.P.H.</b> 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.