



AGENDA

Molecular and Clinical Genetics Panel of the Medical Devices Advisory Committee May 23, 2024

**Discuss, make recommendations, and vote on information regarding the
premarket approval application (PMA) for the Shield, Guardant Health, Inc.**

Panel Chairperson

Andrea Ferreira-Gonzalez, PhD

Designated Federal Officer

Jarrold Collier, MS

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| 09:30 AM | Call to Order
Panel Introductions
Conflict of Interest Statements |
| 10:00 AM | Guardant Health Presentation (75 min) |
| 11:15 AM | Questions for Guardant Health (15 min) |
| 11:30 AM | Break (15 min) |
| 11:45 AM | FDA Presentation (60 min) |
| 12:45 PM | Questions for FDA (15 min) |
| 01:00 PM | Lunch (45 min) |
| 01:45 PM | Open Public Hearing* (60 min) |
| 02:45 PM | Panel Deliberations (60 min) |
| 03:45 PM | Break (15 min) |
| 04:00 PM | Questions for the Panel (60 min) |
| 05:00 PM | Vote (15 min) |
| 05:15 PM | Summary of Panel Recommendations (15 min) |
| 05:30 PM | Adjourn |

*** 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 will then recognize unscheduled speakers as time allows. Only the panel may question speakers during the open public hearing.